A Guide for Improving the Quality of Care of Dialysis Patients

THE NATIONAL ANEMIA COOPERATIVE PROJECT

U.S. Department of Health and Human Services
Health Care Financing Administration

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

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Dear Dialysis Provider:

The Health Care Financing Administration (HCFA) has embarked on a new program entitled "the Health Care Quality Improvement Program" to assist caregivers improve the quality of care provided to Medicare and Medicaid beneficiaries. The End Stage Renal Disease (ESRD) Anemia Cooperative Project is a key HCQIP project developed by the Forum of ESRD Networks, in partnership with HCFA, and with input from representatives of the renal community. Anemia was chosen as the first clinical area to target for improvement because the condition occurs frequently in dialysis patients, outcomes are easily measured and variation in treatment practice exists. The goals of the Anemia Project are to:

- Improve the management of anemia in the dialysis patient population;
- Decrease the proportion of patients with hematocrits less than 31 percent; and
- Educate dialysis care givers on the use of quality improvement techniques to describe and improve key care processes.

Your role in this project, as it is implemented nationally, is to examine your approach to the management of anemia and identify opportunities to improve the anemia status of your patients. To assist you in this effort HCFA and the Forum of ESRD Networks are pleased to provide you with the enclosed copy of "A Guide For Improving The Quality of Care of Dialysis Patients." This Guide was developed to provide you and your staff with information to assist you in identifying opportunities for improvement in your approach to anemia management and in developing quality improvement projects in general. The tools and methods presented in the Guide were field tested by eighteen dialysis facilities across the country during the pilot phase of the National Anemia Cooperative Project (July 1994 - February 1995). Based on input from these facilities, the Guide was revised to make it more user friendly, using a step-by-step approach to quality improvement with emphasis on assessing and improving the treatment of anemia. The lessons and tools included in the Guide can also be used to develop improvement projects in other treatment areas, such as adequacy of dialysis, nutritional status, etc.

Under separate cover, your ESRD Network has also sent you a copy of your ESRD Facility Anemia Profile Report that displays national, network area, state, and facility-specific hematocrit and erythropoietin (EPO) usage information for the last two quarters of 1994 and the first two quarters of 1995. The source of these data is the HCFA billing records which contain information that dialysis facilities provide HCFA when submitting bills for EPO payment. Your Network will be distributing updates to this report to you on an annual basis.

We encourage staff in each dialysis facility to examine their processes and protocols for the treatment of anemia to identify opportunities for improvement. A suggested anemia treatment algorithm is included in the Guide for you to use to compare to your care processes. Use the

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A GUIDE FOR IMPROVING THE QUALITY OF CARE OF DIALYSIS PATIENTS

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FORWARD

The Health Standards and Quality Bureau of the Health Care Financing Administration (HCFA) and the Forum of the End Stage Renal Disease (ESRD) Networks are pleased to provide you with this Guide for your use in developing a quality improvement project focused on improving the management of anemia in your dialysis facility. The Guide is for your use as we implement the National Anemia Cooperative Project. This Project is a cooperative effort between the dialysis provider community, the ESRD Networks and HCFA to promote improvement in the management of anemia through the use of modern quality improvement tools and techniques. It was developed using many of these quality improvement tools and techniques.

The purpose of the Guide is to offer a practical approach to facility staff to use to *jump start* their own process improvement activities. Many resources were used in its development. However, we encourage facility staff to supplement the Guide with additional reading whenever possible. It also offers suggestions for additional reading material.

Improving performance in health care is critical to all health care organizations today. Quality is improved by systematically describing, measuring and analyzing work *processes*. The Guide describes an approach to quality improvement referred to as the *RoadMap*. There are seven steps to the RoadMap which reflect common elements of *continuous quality improvement* (CQI) found in most quality improvement models currently in use by major health care organizations and should, therefore, be adaptable and complementary to existing facility quality programs.

The Project recommends the formation of a facility-based *project team* to perform process analysis and design improvement trials. The team will move through the steps of the RoadMap accomplishing the activities listed within each step. To assist team members, each step contains *Checklists* to use in tracking progress and identifies key terms. The second half of the Guide presents a brief introduction to *Teams, Tools, and Techniques* which are recommended for use with the RoadMap.

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Quality Assessment in Medicare's ESRD Program: A Profile of Change

THE ESRD PROGRAM

Medicare's End Stage Renal Disease (ESRD) program, now more than 20 years old, remains the only nationally funded disease-specific program in the United States, providing payment for life-sustaining renal replacement therapies to more than 250,000 beneficiaries.

The ESRD program is unique within Medicare. It is the only case in which the diagnosis of a categorical disease provides the basis for entitlement of persons at all ages. In addition, both ESRD patients and providers depend on Medicare reimbursement policy to a greater extent than in any other domain of medicine.

The relationship between the Health Care Financing Administration (HCFA) and the renal patient and provider community is also unique. HCFA is responsible to the public for prudently managing the resources it administers and for ensuring that acceptable quality of care is delivered to Medicare beneficiaries. Quality oversight is performed by ESRD Network organizations (ESRD Amendments of 1978, Public Law 95-292, Section 1881 [c]), operating under HCFA contract. Eighteen Networks exist nationally and are described geographically by the number and concentration of beneficiaries in each area. Some Networks represent one state; others multiple states.

The uniqueness of Network organizations lies in the fact that Network operations are accomplished through a partnership between providers, payers, patients, and regulators. Health care professionals and patient representatives voluntarily assist Network and HCFA staff with the responsibilities of federal peer review functions, while at the same time remaining responsive to provider and patient issues.

Networks are the hub for information flow to and from HCFA, ESRD patients and providers. This vertical linkage is a strength of the ESRD system and efforts to modernize, strengthen, and improve this linkage are the major focus of new HCFA-Network activities.

Monitoring Quality

Assessing and improving quality have always been very important parts of professional care. However, despite existing quality efforts, concerns about high morbidity, mortality, and undertreatment of dialysis patients in association with unprecedented cost controls continue to reverberate throughout the ESRD community, driving a continuing imperative to more effectively monitor and assess the quality of care provided to ESRD beneficiaries.[1,2,3,4] Until recently, quality had not been systematically measured on a national basis nor uniformly monitored by the federal agencies responsible for the ESRD program.[1] A quality assessment effort, known as Medical Case Review, was implemented by HCFA through the ESRD Networks during the early 1990s. Medical Case Review included retrospective chart audits performed against a set of dialysis-specific criteria with the results reviewed by members of local Network Medical Review Boards. Though raw data from the Medical Case Review process seemed to validate reports of underprescription and underdelivery of dialysis therapy, significant variation was present among Networks in both data collection techniques and Medical Review Board interpretation of the local data, hampering widespread use of the information for clinical quality improvement nationally.

At the time Medical Case Review was in progress, considerable changes in methodologies for measuring and assessing performance in health care delivery were also taking place throughout the entire health care industry. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced its Agenda for Change in 1987, a research and development initiative designed to make continuous improvement in patient outcomes and organizational performance the central and explicit objective of Joint Commission accreditation activities. By 1991, the first of the revised JCAHO standards was distributed to hospitals.

1. Rettig R, Levinsky NG, eds. *Kidney Failure and the Federal Government*. Washington, DC: National Academy Press; 1991. Institute of Medicine.
2. Held PJ, Levin NW, Bovbjerg RR, et al. Mortality and duration of hemodialysis treatment. *JAMA*. 1991;265:871-875.
3. Held PJ, Blagg CR, Liska DW, et al. The dose of hemodialysis according to dialysis prescription in Europe and the United States. *Kid Intl*. 1992;42(suppl 38):S16-S21.
4. *Morbidity and Mortality of Dialysis: NIH Consensus Statement*. Betheseda, MD: National Institues of Health; 1993; 11-33.

Medical Case Review was a project caught in a changing system. Its design was reflective of the traditional approach to quality assurance and peer review, while at the same time being influenced by new evolving quality concepts. It was an important effort but one focused on individual episodes of care as opposed to mainstream care; historical data; Medical Review Board micromanagement of patient care from afar; and, despite efforts to the contrary, policing providers. Medical Case Review was discontinued in July 1994.

However, despite initial design flaws, many aspects of Medical Case Review were positive-and clearly supportive of the emerging trends in quality management. Most providers demonstrated a key premise of quality management – that work will improve if staff is given the right information and resources. Providers were willing to engage in examining and improving their own practices when objective comparative data were made available to them. Also, a new emphasis emerged on the importance of the Networks in providing education, data feedback, and technical support to providers needing assistance. Providers and Network staff began working together in a more cooperative spirit to promote improvement in the delivery of dialysis treatment and to redesign the quality monitoring system to make it more responsive to the needs of providers.

Initiating Change

Interest in health care performance measures has burgeoned in recent years, and it is all but certain that this *interest* will become expected practice in the years to come. Many quality experts believe that ultimately the public will have access to performance data to make meaningful health care choices. Measuring and reporting on quality in health care is emerging as an urgent and critical responsibility. This mandate reflects the feelings of those who are paying the annual health care bill. They demand to know what they're receiving for their money.[5]

All of medicine is being asked for evidence that patients are receiving medical care of good quality. The ESRD Program confronts this same demand; however, designing a national ESRD quality oversight and improvement program to match up effectively with stringent resource constraints is a major challenge.

5. O'Leary DS. The measurement mandate: report card day is coming. *JCAHO J on Quality Improvement.* 1993;19(11):487-491.

For example, formidable obstacles exist to installing modern quality measurement and assessment techniques in the ESRD setting. With over 70% of dialysis services currently provided in free standing clinics, providers are often professionally isolated from quality management and assessment information and tools.[6] Many dialysis facilities also lack access to computers for monitoring quality indicators and staff to work with the data. Some ESRD providers, long accustomed to working with federal regulations, continue to view quality assurance as a requirement (imposed on treatment units by the federal government) to be delegated to a QA coordinator for paper compliance to shield the unit from adverse effects, while others experience a certain complacency and lack of motivation.[1] And finally, physician resentment of perceived government intrusion into medical practice underscores a longstanding resistance to change.

HCFA and the Networks recognize both the need to change quality assessment methods and these inherent obstacles to change.

Charting a New Course

System redesign began in early 1991. With the landmark IOM report, *Medicare: A Strategy for Quality Assurance*,[7] as a guiding document, the Forum of ESRD Networks conducted a quality planning session in Washington (January 1991) to facilitate early discussions of new quality strategies. The IOM report stressed the need for change throughout the Medicare Program and suggested that the concepts of total quality management (TQM) and continuous quality improvement (CQI), though still unproven in the health care community, were worthy pursuits. Subsequently, the Forum Quality Improvement Committee began work on developing CQI training tools and programs.

In April 1991, a second report from the IOM, *Kidney Failure and the Federal Government*, expanded the principal quality themes from the Lohr report to the ESRD program and conceptualized an agenda for change.[1] This change would eventually focus on *examining outcomes of care processes* with the intent of reducing clinically ineffective care and improving overall care.

1. Rettig R, Levinsky NG, eds. *Kidney Failure and the Federal Government*. Washington, DC: National Academy Press; 1991. Institute of Medicine.
6. *United States Renal Data System: USRDS 1993 Annual Report*. Bethseda, MD: National Institute of Diabetes and Digestive and Kidney Diseases; 1993. National Institutes of Health.
7. Lohr KN, ed. *Medicare: A Strategy for Quality Assurance*. Washington, DC: National Academy Press; 1990. Institute of Medicine.

HCFA officially announced its intent to change to a new approach in March 1992. The official notice of change was called the Health Care Quality Improvement Initiative,[8] later renamed the Health Care Quality Improvement Program (HCQIP) for the ESRD Program. The initiative was announced at the spring meeting of the Renal Physicians Association and was viewed as a welcomed change.

Overall, the HCQIP would strive to enhance the ability of ESRD Networks to assist providers in their individual efforts to improve care, and promote increased cooperation and collaboration in developing new quality assessment instruments to ensure their usefulness to ESRD providers.

Between March 1992 and July 1994, HCFA, the Forum of ESRD Networks, and provider groups participated in a series of events that began the process of change including: training for Network leaders in the new concepts of TQM/CQI, forums focused on collecting ideas for the design of the new system, establishment of a new quality agenda, and implementation of a pilot study to test the new approach.

Creating a New Quality Agenda

The new framework for quality is a combination of two separate but complementary activities: *outcomes assessment and continuous quality improvement.*

Outcomes Assessment concerns the measurement, monitoring and feedback of data. It requires the development of instruments and measures, and it implies a need for research to validate and interpret these measures. The role of the outcomes assessment team is to provide feedback of information to clinicians for their use in improving care processes.[9] HCFA and the Networks serve as the assessment team in the HCQIP approach.

The current *agenda* for the HCQIP includes the following outcomes of interest and corresponding indicators:

Outcomes of Interest:	**Process Indicators:**
Management of Anemia	Hematocrit levels
Adequacy of Dialysis	Urea reduction ratios
Nutritional Status	Serum albumin
Blood Pressure Control	Pre- and postdialysis blood pressure values

8. Jencks SF, Wilensky, GR. The health care quality improvement initiative: a new approach to quality assurance in Medicare. *JAMA.* 1992;268:900-903.

9. *A Guide to Establishing Programs for Assessing Outcomes in Clinical Settings.* Oakbrook Terrace, IL: JCAHO; 1994.

The results of HCFA's first attempt at indicator measurement are described in the 1994 and 1995 ESRD Core Indicators reports.[10,11] The core indicators describe key characteristics of care established by nephrology community consensus over time.

The collection of information on core indicators represents a transition from Medical Case Review to population-based assessment of care. It is anticipated that core indicators will be monitored yearly and that national and Network-specific data comparisons will be generated for use by the Networks and individual facilities in planning their quality activities. This approach is in keeping with the initiatives of other heath care quality organizations. Data banks are being established to support quality review activities associated with accreditation and regulation such as the JCAHO, the Health Plan Employer Data and Information Set (HEDIS), state agencies, private insurers and the evolving Medicare Quality Indicator System.

Continuous Quality Improvement is an approach to improving a process that begins with an assessment of current knowledge of the process (including comparative performance data), searches for causes of performance variation and plans for process improvement. Clinicians are expected to examine their own processes of care and make the appropriate improvements. Progress is monitored through ongoing collection of process outcome data.

The National Anemia Cooperative Project promotes the linkage of outcomes assessment to clinical process improvement in the dialysis facility to improve the management of anemia. The project design includes the distribution of facility-specific reports of organizational performance related to the management of anemia, together with a quality improvement guide containing a stepped approach for providers to use as they begin the journey of process improvement.

10. *1994 ESRD Core Indicators Project Initial Results, Opportunities to Improve Care for Adult In-Center Hemodialysis Patients.* Baltimore, MD: Health Care Financing Administration; December 1994. Health Standards and Quality Bureau.

11. *1995 Annual Report, ESRD Core Indicators Project.* Baltimore, MD: Health Care Financing Administration; January 1996. Health Standards and Quality Bureau.

Redesigning quality assessment in the ESRD Program thus far has been an exciting and challenging experience for all involved. It has required:

- Commitment from top leadership, including HCFA staff and recognized practitioners in the field.
- An assessment of system capability to change to new ways.
- Implementation plans and a strategy for deployment.
- Training for management (Network officers, Medical Review Board chairpersons and staff).
- Pilot testing of the new approach.
- Involvement and cooperation of key stakeholders such as facility staff and industry leaders.

Clinical outcomes assessment is at an early stage of development and the application of outcomes assessment to continuous quality improvement must be learned. Outcomes assessment must be built upon a foundation of expected performance (recognized standards of care and practice guidelines) over time. It will be necessary to judge outcomes in the context of the state-of-the-art of medicine and rational expectations. Equally important will be the need for providers to learn the tools and techniques of CQI. After almost five years of preparation and trials, HCFA and Network staff are now prepared to assist dialysis providers with the work of measuring, monitoring, and improving care systemwide in the ESRD Program.

The Model: The Health Care Quality Improvement Program

GLOBAL VIEW OF THE INITIATIVE

Projects to improve specific aspects of mainstream care are central to Medicare's Health Care Quality Improvement Program, including the End Stage Renal Disease (ESRD) Program. HCQIP projects are designed as partnerships between peer review organizations and hospitals, clinics, health plans, and physicians in which partners:

- Agree on an aspect of care that may need improvement – develop and adopt quality indicators.
- Collect data and use the indicators, along with professional standards of practice, to confirm the need for improvement.
- Devise and carry out steps to bring about change, generally through improving the system of care.
- Use indicators to measure success.

The HCQIP implies profound changes to current quality assessment activities for all of Medicare. For example, the processes, criteria, immediate objective and ultimate methods for review will all change.

Four important forces drive these changes: variations research, studies of peer review, new models for quality improvement, and the guidelines movement.

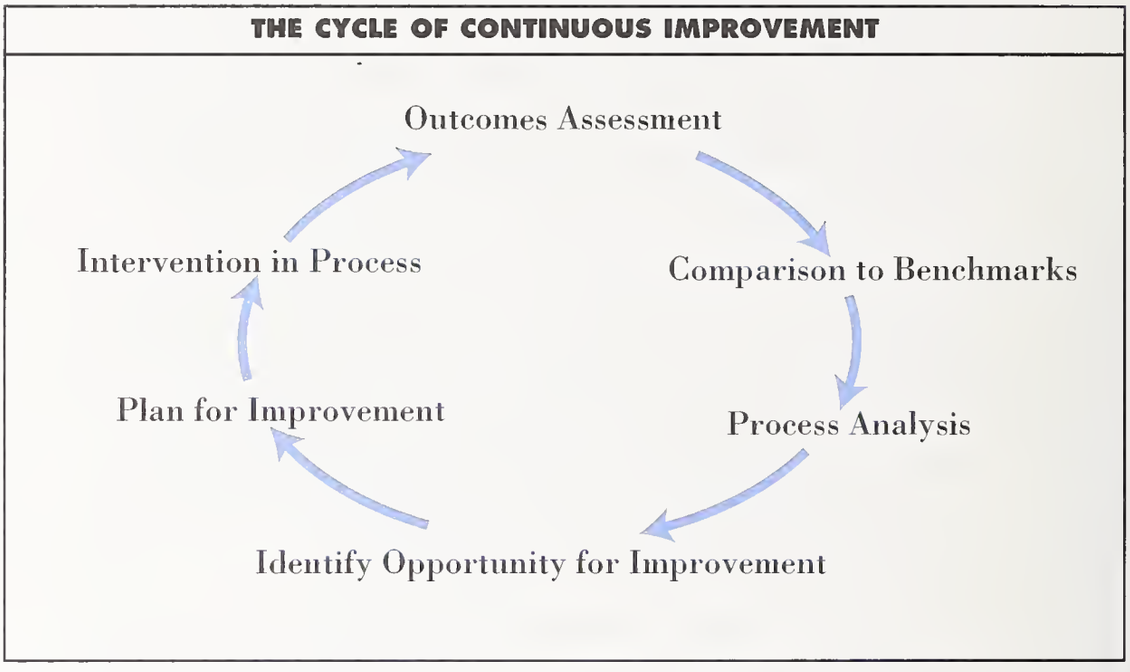
- *Variations research* has shown that patterns and outcomes of care vary from area to area and from provider to provider in ways that cannot be explained from known variations in patient sickness. Accumulating evidence indicates that variation in risk-adjusted outcomes reflect variations in appropriateness of care.
- *Studies of peer review* show that physician review of medical records to determine quality of care has only modest reliability even in research settings. Additionally, measuring the impact of actions based on case-by-case review is almost impossible.
- *New models for quality improvement* focus on improving the processes producing typical care rather than using inspection to correct unusual errors. They argue that substandard care generally results from poor process design, inadequate information, and poor training rather than from stupidity, indifference or greed. These quality management models suggest that we should inspect care processes in order to identify patterns of errors, not to correct individual errors.
- *The guidelines movement*. The federal government and professional groups have started an expanding process of developing and publishing practice guidelines, which provide a potential basis for quality improvement efforts.

The HCQIP's most important objective will be to redirect attention from the actions of a few outliers to improving the quality of mainstream medical care. While previous efforts to improve quality often consisted of exchanges of adversarial letters, the HCQIP seeks to stimulate the creative involvement of physicians in quality improvement activities. This redirection also emphasizes quality measures based on practice guidelines and parameters rather than the more subjective judgments of individual physicians reviewing individual cases.

The Cycle of Continuous Improvement

The most important element for quality improvement under HCQIP is a collaborative effort between ESRD Networks and the health care community to improve specific aspects of care. The HCQIP model promotes collaboration through two fundamental activities: outcomes assessment and continuous quality improvement .

THE CYCLE OF CONTINUOUS IMPROVEMENT



HCFA and the Networks serve as the outcomes assessment team: collecting and profiling data, providing feedback to clinicians, assisting in explaining and clarifying data. and teaching process improvement methods. The role of clinicians is to use the outcomes data to: compare current practice to professional standards (current performance data), and to initiate process improvement as needed within the privacy of their own practice settings.

To succeed, Networks and dialysis providers must *build capacity* for partnership and for analyzing and improving system performance – whether that system is a dialysis unit or the entire ESRD program. Building *capacity for partnership* means new attitudes and a willingness to move away from business-as-usual to new, innovative methods that require sharing knowledge and control, and teaching/coaching rather than mandating. Building *capacity for quality improvement* will mean learning the science of quality measurement and assessment. Increasing overall capacity for improvement is important both as a foundation for specific objectives (i.e., improving the management of anemia) as well as an investment for future initiatives.

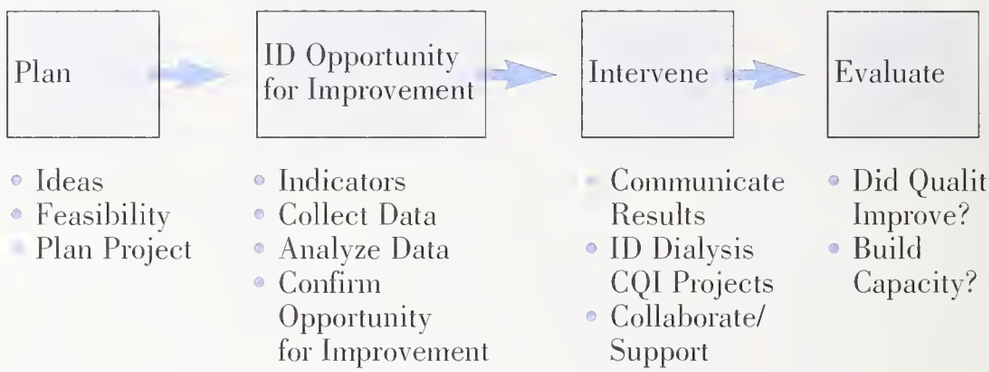
Many health system reform proposals envision government support for continuous quality improvement in health care. Cooperative improvement projects, such as the Anemia Project, provide test sites and models for ways to provide such support. Cooperative projects use quality indicators to determine need for a project and to measure success. In turn, cooperative projects provide a detailed examination of practices to either validate an indicator as a measure of quality or show where refinement is necessary. This approach provides a model for validating the national quality indicators that are part of many new health care systems.

HCQIP Process

The HCQIP is, itself, a process and is illustrated in the diagram below. It begins with a plan, requires verification that an opportunity for improvement exists, provides information to clinicians with which they can improve their processes of care, and continuously evaluates the effectiveness of the overall approach.

HCQIP FOR THE ESRD PROGRAM

HCQIP Process



Develop a Plan

Planning involves achieving community consensus on priorities for improvement, designing a data management system; and describing intervention techniques.

Planning goal: Shift the focus of Network activities to:

- Professional review of patterns and outcomes of care. Instead of having clinicians use essentially intuitive local criteria to find problems in individual cases, Networks will use explicit, more nationally uniform criteria to examine patterns of care and patterns of outcomes. Networks will focus primarily on persistent differences between the observed and the achievable in both care and outcomes and less on occasional, unusual deficiencies in care. Without a pattern of problems/concerns, there is no context for change and no way to evaluate the effects of change.
- Coordination and education of the provider and consumer communities.
- Collaborative clinical projects developed with the community to improve the administration of the Federal ESRD program and to improve our knowledge of processes and outcomes of ESRD care. Networks will help providers identify problems and their solutions by monitoring patterns of care and outcomes, and by allowing providers to conduct the more intrusive and detailed study of who, when, and why.

The ESRD HCQIP Plan is operationalized through two projects:

- *The Core Indicators Project* establishes the national clinical database and methodologies for assessing variations in care. The indicators included in the database are clinical values felt to be descriptive of the outcome of the care process.
- *The National Anemia Cooperative Project* is a model for linking core indicator data to clinical process improvement. Dialysis providers will be asked to assess their own performance (using comparative data) and to search for ways to improve care within their own system.

Identify an Opportunity and Verify that Improvement is Possible

Improvement goals: Focus on the appropriateness and effectiveness of routinely delivered care by choosing an improvement opportunity based on established criteria and confirming that variation exists and improvement is possible.

- Many ideas for clinical improvement projects were suggested by members of the ESRD provider community. Verifying that an improvement opportunity existed required documented variation in care and confirmation that improvement was possible. The criteria used to select Anemia as the first national cooperative project are listed on pages 19-21.

Intervene

Intervention goals: Provide information and tools to clinicians to support process improvement.

- Comparative performance data will be provided to dialysis facilities, along with assistance in interpreting the data and instructions for ongoing data submission.
- Educational materials will be provided to assist providers in developing skills for process improvement.
- Whenever possible, HCFA and the Networks will serve as a clearinghouse for the distribution of practice guidelines and treatment protocols (algorithms).
  - Each Network will develop a plan for the use of the core indicator data.
  - Education and technical support will be made available from the Network offices.

The National Anemia Cooperative Project operationalizes the intervention goals by directing all activities toward one particular documented opportunity for improvement – management of anemia – and providing the following information and tools:

- Facility-specific data and comparisons of performance to national and regional data.
- A treatment algorithm for comparison of performance.
- A guide for process improvement activity.

Evaluate

Evaluation Goals: Evaluate the appropriateness and effectiveness of the HCQIP process – was the right approach used to stimulate improvement activities and was it used as designed?

The ESRD HCQIP will be evaluated over the course of the three-year Network contracts. The evaluation will address the following issues:

- Can ESRD Networks collect, analyze, and disseminate information regarding national, regional, and center-specific treatment patterns of process and outcomes of care?
- Will dissemination of this information be associated with improved quality-indicator patterns, especially where Networks and facilities have implemented quality-improvement activities?
- Will the dissemination of general ESRD information, national and regional feedback about practice patterns, and quality-improvement tools, such as computer software, to treatment centers improve their management of anemia and adequacy of dialysis?
- Will the implementation of the ESRD HCQIP be associated with improvements in regional and national patterns of anemia care and adequacy of dialysis?

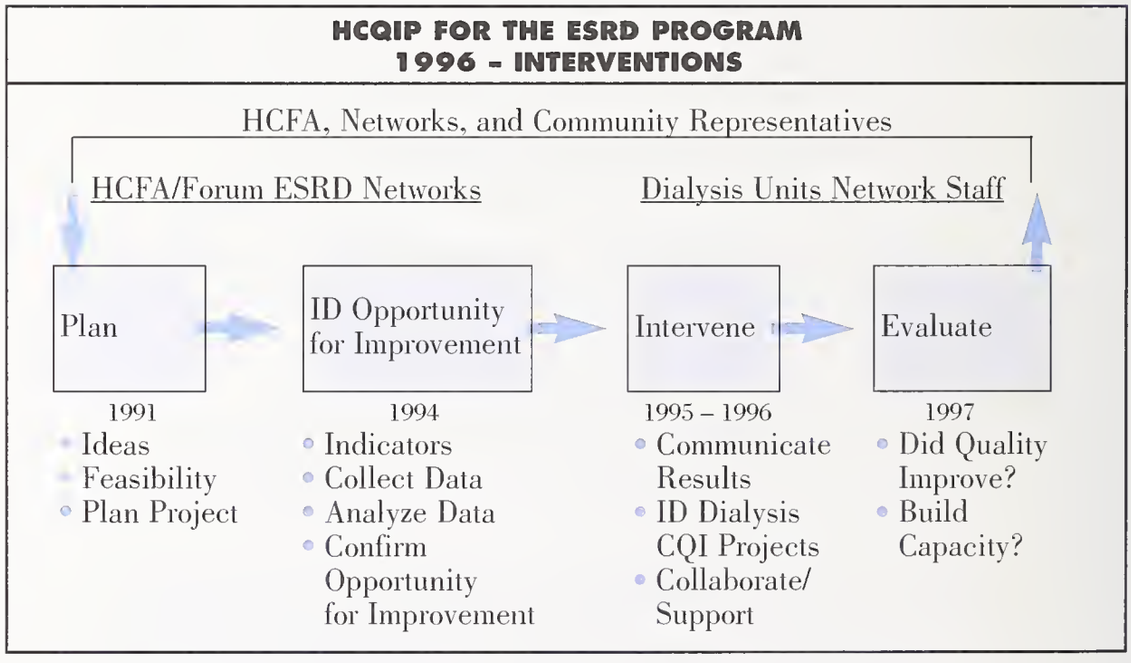
HCFA is committed to working with the ESRD Networks, physicians, providers, consumers and other groups to refine quality assessment methods, and to making the improvement process consistent and open.

In summary, the HCQIP for the ESRD program gives the ESRD Networks and the HCFA a chance to demonstrate that cooperation between the ESRD Networks and the providers can *measurably* improve process and outcomes for dialysis patients. The HCQIP approach will, at first, be unfamiliar to most physicians and other health care professionals, but the HCFA plans to promote skills development through national cooperative projects that are *designed* to demonstrate results. Measurement of improvement is built into each activity.

In time, Network staff will be able to analyze variations in patterns and outcomes of care. Of particular concern will be:

- Examining the variations in *processes* of care and the ways in which care diverges from what is known or believed to be effective.
- Examining variations in the *outcomes* of care, both to identify remediable sources of poor outcome and to validate assumptions about which processes are appropriate.

Where are we today in the HCQIP Process?



THE NATIONAL ANEMIA COOPERATIVE PROJECT

The goals of the Anemia Cooperative Project are to improve processes and outcomes related to the management of anemia in dialysis patients, and to educate facility staff in the use of reference data and performance measurement and improvement tools and techniques.

Management of Anemia – Criteria for Selection

Why was anemia chosen as the first outcome of interest? Dr. Paul Eggers explains the rationale in an article published in the *American Journal of Kidney Diseases*.[12] Excerpts follow:

> One of the most prevalent side effects of end stage renal disease is anemia. Nonfunctioning kidneys do not produce erythropoietin, a substance which induces the production of red blood cells by the bone marrow. Short of receiving a kidney transplant there are only a few methods of trying to remedy the shortage of red blood cells. The most common method up to 1989 was blood transfusion. This technique was less than optimal for a variety of reasons. First, the impact is short lived. Red blood cells have a life expectancy of about 3 months and need to be continually replaced. A transfusion increases the red blood supply immediately but then gradually loses effectiveness over time. Frequent blood transfusions also increase the body's anti-bodies to foreign tissue making patients less able to find suitable transplant matches. In addition, there is a small risk of infection such as HIV or hepatitis from transfusion. Iron supplements alone have been shown to be effective in raising hematocrit levels for some persons but have never been widely used. Beginning in June 1989, recombinant human erythropoietin (EPO) was approved for payment for Medicare ESRD patients on dialysis. Since that time, it has rapidly been adopted as the therapy of choice for the treatment of anemia of dialysis patients.

12. Eggers PW, Greer J, Jencks S. The use of Health Care Financing Administration data for the development of a quality improvement project on the treatment of anemia. *Am J Kid Dis.* 1994;24:247-254.

Erythropoietin has been shown to be effective not only in raising hematocrit levels, but also in improving such quality of life measures as improved appetite, exercise tolerance, sexual function, energy activity, life satisfaction, and general well-being. In addition, it has shown evidence of increasing patient tolerance of dialysis therapy. It has not been shown to be effective in improving work status. Quality of life is an inherently difficult outcome to measure. Measurements based on perceived, or subjective, quality of life have previously shown that dialysis patients report surprisingly high levels of satisfaction with their lives.

In a discussion of the HCQII (precursor to the HCQIP) by Jencks and Wilensky, five criteria are listed which should be considered in setting priorities for targeting clinical areas.[8] Similar criteria are also found in the other quality literature sources. Treatment of anemia in dialysis patients fits these criteria:

1. *The condition is frequent in the Medicare population.*
   This is certainly true for anemia, which is nearly universal among dialysis patients.

2. *Guidelines for care are well-defined and widely accepted.*
   There are no formally established guidelines for the treatment of anemia in dialysis patients. However, there is widespread consensus among nephrologists that anemia is a major quality of life problem for patients and that the proper use of erythropoietin can alleviate this condition. A description of current approach to treatment of anemia in dialysis patients has been developed by the Forum of ESRD Networks' Quality Improvement Committee and circulated as an algorithm of care to nephrology organizations for further consensus and endorsement.

3. *Methods are available to measure outcomes and risk factors.*
   A commonly used clinical measure of anemia is hematocrit. Raised hematocrit levels improve quality of life, and EPO administration has been shown effective in raising hematocrit. This measure is collected routinely by HCFA on the outpatient billing form used to bill for erythropoietin.

8. Jencks SF, Wilensky, GR. The health care quality improvement initiative: a new approach to quality assurance in Medicare. *JAMA.* 1992;268:900-903.

There are at least two known weaknesses to this measure. First, hematocrit levels are not routinely available to HCFA for persons not receiving erythropoietin. Therefore, it is not possible to identify dialysis patients who should receive therapy but do not. Secondly, for persons receiving erythropoietin, there is no measure available to HCFA of hematocrit levels prior to initiation of therapy. Therefore, degree of improvement in anemia cannot be measured.

The hematocrits, however, can serve as a basis for facility comparisons and as initial descriptors of variation among providers. Supplemental data collection and analysis at the provider level will be necessary to address identified weaknesses.

It is not clear that risk factors are a significant problem for this treatment. Early studies have shown that hypertension is a potential adverse side effect of erythropoietin treatment, although it seems to be controllable. However, patients with poorly controlled hypertension may not be good candidates for erythropoietin therapy. There is also some concern that vascular access clotting may be an adverse side effect.

4. *Conforming with guidelines does not require large changes in available skills or resources.*
   Provision of erythropoietin and monitoring of hematocrit levels are relatively straightforward and are easily accomplished.
5. *There is a substantial, clinically important difference between guidelines and actual practice and there is substantial variation in outcomes.*
   It appears from routinely collected HCFA data that achieved hematocrit levels in the dialysis population (under erythropoietin treatment) are considerably less than suggested by the clinical trials. Whereas the clinical trials showed that over 90% of patients can achieve hematocrit levels over 30%, HCFA billing data show that only about 45% of patients achieve this level.

This review of criteria qualifies anemia as an acceptable outcome of interest for the HCQIP in the ESRD program.

What are Dialysis Staff Expected to Do?

- Examine their approach to the management of anemia and work toward improved patient outcomes (for example: improve anemia status as measured by mean or median hematocrit level; decrease the percentage of patients with hematocrits < 31%).
- Monitor key process indicators. All facilities will be encouraged to collect hematocrit information on all patients at least monthly, determine the facility's average or median hematocrit level, plot this value on a run chart, and monitor the run chart over time. Those facilities with performance below certain levels may be asked to examine their care processes and develop an improvement project.
- Submit information to the Network. For all facilities, the Network may at any time request mean or median hematocrit level data and a copy of the facility's run chart. For poorer performing facilities, the Network may request hematocrit data on all patients, a description of the facility's plan for improvement, and/or other information.
- Complete a follow-up survey (in six to ten months) to obtain information on what actions have been taken to improve the anemia status of its patients.

What are Networks expected to do?

- Distribute the ESRD Facility Anemia Profile Reports to all dialysis units.
- Review Anemia Profile Reports, Core Indicators data, other Network data to monitor facility performance.
- Networks may require dialysis facilities to:
  1. Develop, implement and submit their improvement plan to the Network.
  2. Send hematocrit levels on all patients and the corresponding run charts to the Network.
  3. Submit other information to the Network as requested.
- Assist dialysis facility staff in the development of quality improvement projects.
- Identify best practices or successful intervention strategies that can be shared with all dialysis facilities to improve patient care.
- Survey facilities at the end of six to ten months to find out what actions they have taken to improve their patients' anemia status.

The Expected Outcomes of the Anemia Project

The expected outcomes of the Anemia Project will be:

- A decrease in the *percentage of patients* reporting hematocrits below 31%.
- *Fewer patients* with hematocrits below 28%.
- An increase in the use of the *tools* of quality improvement.

NOTES:

MEASURING, ASSESSING AND IMPROVING PERFORMANCE IN THE MANAGEMENT OF ANEMIA

Admittedly, designing a national quality oversight and improvement program is a major challenge. The science of quality assessment is undergoing a major paradigm shift while at the same time, the nation is in the throes of health care reform. Installing a new approach to quality assessment within the ESRD program in such a kinetic environment is indeed *charting a course in stormy waters* and requires a vision of new directions that, hopefully, will be in sync with the changing world around us.

PARADIGM SHIFT
A paradigm is an example serving as a fixed model. When the model is altered by process, a new paradigm is formed creating a shift in the paradigm or example.

In many *blueprints* for health care reform, architects are building in a national framework for quality which includes a number of common features. including[13]:

- A policy principle that health plans are responsible for the improved health of the populations served.
- The creation of a national health care information database that will serve as the foundation for quality-related activities.
- The promise of a *report card* for consumers.
- The establishment of a state-based, patient complaint office to permit redress for consumers who feel that their benefits have been curtailed or their care compromised by competing health plans.

To a large extent, the ESRD program is at an advantage in addressing these reform principles. An emphasis on improved health for the ESRD population is reflected in the Networks' new mandate to monitor **patterns and trends of patient care** within the dialysis population. ESRD providers are beginning to use both national data and regional Network data for quality related activities. Complaint systems are being strengthened through the increased cooperation and data sharing between Network offices and state survey agencies.

MONITORING
A planned, systematic and ongoing process to gather and organize data, and aggregate results.

13. Health reform and the quality imperative. *AMPRA Review.* Washington. DC: American Peer Review Assn; Fall/Winter 1993/1994.

Still, these activities, while seemingly broad-reaching and comprehensive, do not address and satisfy the more important task of measuring and improving the processes of care that are the underpinnings of data. A new system is needed that enables the renal community on a national basis, or the dialysis unit on a local basis, to harness the statistical power of a large database, select outcomes of interest, examine provider performance, implement education and improvement, and report results.

The HCQIP (Health Care Quality Improvement Program) project described in this Guide introduces HCFA's new approach to systemwide quality assessment, an approach that will attempt to link outcomes data to clinical improvement. The ESRD Program is uniquely positioned within Medicare to install this new approach which may prove to be the model for future health care measurement efforts. Of particular concern will be the establishment of appropriate linkages with the provider community and proving their effectiveness. This will take time and will require continuing refinements to the system.

The Anemia Project was designed to test and support the linkage between clinical indicator data and provider performance. A pilot project was conducted between July 1994 and February 1995 to test the system at all levels – HCFA, Networks, and the dialysis facility. HCFA/Network activities included producing data profiles from HCFA administrative records, training Network staff to assist providers in using the data, and coaching the pilot teams. Facility staff were asked to review their own approach to managing anemia and compare their current performance to a nationally recognized clinical algorithm, identify key areas in need of improvement, and institute improvement efforts utilizing quality improvement strategies and techniques.

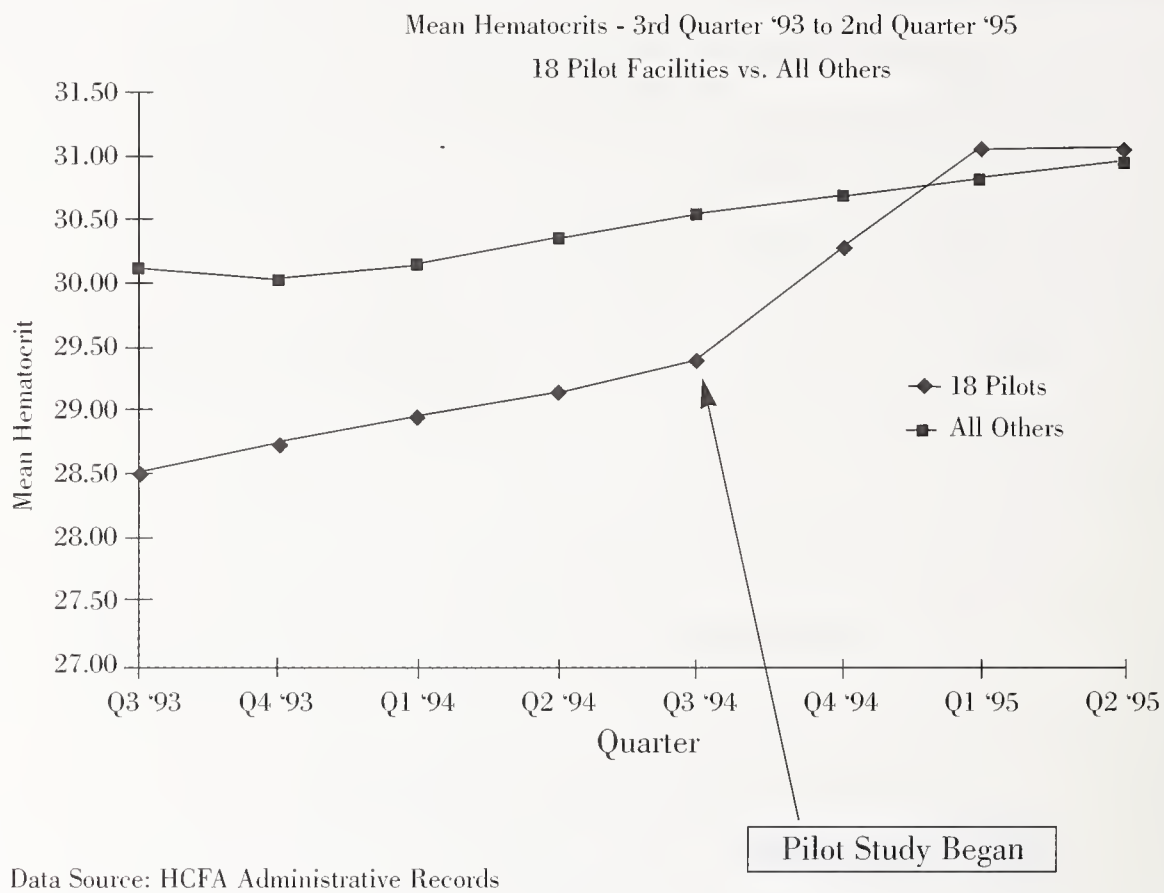
CLINICAL ALGORITHM
A graphic outline that describes each step in the thought process of clinical diagnosis and treatment.

The Anemia Project pilot was concluded and evaluated in the spring of 1995. Comments were received from the participants, recommendations considered, and revisions made where indicated. Preliminary results indicated the following:

- About the approach
  - 75% would continue to use the RoadMap.
  - 81% felt the approach strengthened their understanding of quality improvement.
  - 90% felt the approach provided new knowledge.
- About the comparative data compiled by HCFA
  - 85% felt that data comparisons stimulated further examination of practice.
- About the Anemia Algorithm
  - 88% used the algorithm as a benchmark.
  - 65% identified differences between the algorithm and their practice.
- Overall
  - 100% identified an opportunity for improvement.
  - 86% implemented an improvement trial.
  - 79% felt that they could continue on their own.

Figure 1 shows the change in mean hematocrit reported by the 18 pilot facilities compared to all others between the third quarter 1993 and the second quarter 1995.

Fig. 1 **HCFA ANEMIA PROJECT PILOT FACILITIES RESULTS**



Data Source: HCFA Administrative Records

HCFA and the Forum of ESRD Networks are committed to making changes as needed and to ensuring that the results of the Anemia Cooperative Project are meaningful and measurable. To that extent, the format for the ESRD Facility Anemia Profile Report prepared by HCFA and the Guide have undergone extensive revisions prior to this release.

The remainder of this Guide focuses on the *RoadMap for Improvement.* The RoadMap is intended to promote a systematic approach to process investigation and improvement as well as the development and use of quality improvement tools and techniques. Providers are encouraged to use the RoadMap to guide them through their measurement and improvement activities.

Each provider's experience with process improvement (and with the application of the RoadMap) will be different and improvements will be different from one institution to another. Eventually, variations in practice will be identified, improvements implemented, and patterns of care that can be linked with better performance will surface to benefit the entire system.

One final note. The Guide represents an outline of selected basic activities. It is not meant to be all-inclusive. Many resources were used in preparing the Guide and users are strongly encouraged to do supplemental reading in all areas.

NOTES:

STEP ONE

STEP TWO

INTRODUCTION TO THE USE OF THE ROADMAP

The ROADMAP outlines a seven-step approach for systematically identifying, designing, implementing, and evaluating a process improvement project. The focus of this Guide is on improving the anemia status of dialysis patients. However, the techniques discussed in each step of the ROADMAP can be applied to the improvement of any care process.

Following the steps outlined in the RoadMap will help your facility's quality improvement team systematically:

- Analyze its care processes.
- Determine why processes may not be yielding the desired patient outcomes.
- Design and implement an improvement trial.
- Evaluate the effectiveness of the implemented change.
- Document all the actions taken along the way so that the improvement project can be described and shared with others.

Each step of the ROADMAP begins with an objective and activities for meeting the step's objective. The step's activities are discussed, providing the reader (quality improvement team) with ideas/assistance in performing the activities. Each step ends with a summary *How To* conduct/complete the step. and a *Checklist* for reviewing the team's performance before beginning the next step in the ROADMAP.

The ROADMAP was prepared in a logical stepped approach for developing and implementing a quality improvement project. However, depending upon the experience and knowledge of the facility's quality improvement team and commitment of management, some steps can be skipped or modified to fit the facility's established quality improvement program.

A ROADMAP FOR IMPROVEMENT
SUMMARY OF ACTIVITIES

Step One: Make a Commitment to Improve Care

Activities

- Engage leadership.
- Assemble project team and assign team roles.
- Review purpose of Anemia Project and discuss importance and potential impact on overall unit operations.
- Choose method for process improvement.
- Identify team training needs and institute as needed.
- Achieve consensus on team readiness to proceed.

Step Two: Outcomes Assessment – Clarify Current Knowledge of Process Performance and Write an Opportunity Statement

Activities

- Review and discuss ESRD Anemia Profile Report from HCFA.
- Identify customer expectations.
- Plan and collect current baseline data.
- Manage the data.
- Produce data displays for team analysis.
- Write an opportunity statement.
- Begin recording team progress (storyboard/storybook).

Step Three: Describe and Analyze the Basic Process and Identify Sources of Variation (process analysis)

Activities

- Understand the concept of variation.
- Conduct process analysis – describe the process.
- *Compare* the facility's process to external references (anemia algorithm, protocols and other external references such as practice guidelines, when available).
- Brainstorm for *potential sources of variation* (causes of low hematocrits).
- *Confirm* which sources are real (plan, collect and display data).
- Select one key source of variation for further investigation and action.
- *Continue monitoring* the process (using facility mean or median hematocrit) and update run chart.
- Continue progress report (storyboard/storybook).

Step Four: Search for Root Causes of Variation and Select an Area for Improvement

Activities

- Review activities conducted in Step Three (concept of variation, process analysis).
- Perform process analysis (as detailed in Step Three) on confirmed source of variation.
- Confirm root causes of variation (plan, collect and display data).
- Select an opportunity for improvement. (Link root cause to outcome measure and the opportunity statement from Step Two.)
- Continue to monitor process and update run chart.
- Continue progress report (storyboard/storybook).

Step Five: Design and implement an improvement trial

Activities

- Generate as many ways as possible to improve.
- Clarify and analyze each potential solution and reach consensus on which improvement to try first.
- Design a plan for implementing the trial improvement.
- Initiate the trial improvement.
- Continue to monitor and update run chart.
- Continue progress report (storyboard/book).

Step Six: Evaluate the Improvement Trial

Activities

- Evaluate improvement trial using established criteria.
- Compare results with the *desired state* from Step Two.
- Check for and address new problems created by the solution.
- Inform management of trial results so that change can be implemented systemwide (Step Seven), or return to Steps Three and Four to search for other sources of variation and/or to Step Five for root causes.
- Continue to monitor process with run chart.
- Continue progress report (storyboard/storybook).

Step Seven: Act on the results

Activities

- After consulting with management, act on results.
- Prepare to report results of project.

THE ROADMAP AT A GLANCE

Step		Questions to Be Answered	Generate Ideas
One	Focus on a process; assemble and train a team.	What are we about to do?	Ideas for CQI projects.
Two	Clarify knowledge of current performance; compare; describe desired state.	Where are we? How are we compared to others? Where do we want to be?	Ideas for measuring current process and desired state.
Three	Describe and analyze care process; identify sources of problems.	How does the current process work? How do we work compared to others? How is our work different?	Ideas of potential sources of variation.
Four	Search for root cause of variation; select an opportunity for improvement.	Which documented sources of problems are impacting the most on care? What is the cause of problems in each area?	Ideas of root causes of variation.
Five	Generate potential solutions; select, plan and implement a trial solution.	How can we get to where we want to be? What should we do first? What's the best way to do it?	Ideas on how to solve the problem; how to implement solutions; how to monitor and evaluate the trial improvement.
Six	Evaluate the trial improvement.	Have we implemented the trial improvement correctly? Have we followed the monitoring plan? Are we improving? What are we learning?	_____
Seven	Act on and communicate results.	Should we implement systemwide change? Does management support change? If not, should we continue to search for other root causes?	Ideas for planning systemwide change.

Gain Consensus	What to do Before Proceeding to the Next Step
Agree with goals of the project; team composition; training.	Train team in theory and application of CQI tools and techniques; choose a progress report format; choose a process improvement methodology.
Agree on current level of performance and desired state.	Review external data; collect new baseline data; verify gap between current and desired performance; start run chart and monthly monitoring; initiate progress reports.
Agree on a description of the current process and key sources of variation.	Flow chart current process; compare to practice guideline; brainstorm cause-and-effect for sources of variation; collect data to validate hypotheses; use Pareto to display results; continue run chart and progress report.
Agree on root cause of variation and an opportunity for improvement.	Flow chart and brainstorm cause-and-effect of key, documented source of variation; collect data to confirm root cause; isolate improvement opportunity; continue run chart and progress report.
Agree on a design and implementation plan for a trial improvement; agree on criteria for evaluating trial.	Brainstorm possible improvements; analyze strengths and weaknesses (force-field analysis); establish criteria for selection (solution matrix); establish time lines and a plan for monitoring and evaluating the trial; update run chart and progress report.
Agree on effectiveness of trial.	Evaluate improvement trial using established criteria; compare results with desired state; check for new problems; inform management and decide to implement change systemwide, or, return to Steps Three and Four to search for other sources of variation and/or root causes; update run chart and progress report.
Agree to a new plan for systemwide change; or, recycle to Steps Three or Four.	Prepare to report results of project (storyboard); communicate results throughout the organization; continue to monitor process.

NOTES:

STEP ONE

STEP TWO

OBJECTIVE

Make a Commitment to improve care

ACTIVITIES

- Engage leadership.
- Assemble project team and assign team roles.
- Review purpose of Anemia Project and discuss importance and potential impact on overall unit operations.
- Choose method for process improvement.
- Identify team training needs and institute as needed.
- Achieve consensus on team readiness to proceed.

DISCUSSION POINTS

◆ Engage Leadership

Measure
To collect quantifiable data about a dimension of performance of function or process.

Assess
To transform data into information by analyzing the data.

Leadership commitment to the *need* to measure and assess quality is fundamental to quality improvement, and leadership training is a first step. Quality principles cannot be installed within an institution without commitment from the top. An organization's leaders should become familiar with the philosophy and principles of quality management and their application to health care services. Quality *training* stresses the importance of leaders becoming involved in understanding how quality assessment is accomplished and *what the results mean*. Active involvement means *understanding quality assessment methods and providing resources and skills training to other staff*, enabling them to carry out the more intensive work of process analysis and identifying root causes of problems.

Root cause
The primary cause of the problem being addressed and toward which the solution is directed.

Quality improvement philosophy clearly places *accountability* for the quality of services provided within the institution among its top leaders (dialysis facility's governing board, medical and nursing directors, administrators). It also identifies the *responsibility* of leaders to ensure that key services are assessed and found to meet an acceptable level of care. Case law[14] has affirmed that the governing body of a hospital is legally accountable and that the hospital has the duty to monitor the quality of care provided to patients.

Placing accountability and responsibility for quality within the governing board illustrates the notion that the physician alone is not fully responsible for institutional outcomes of care. While physicians drive the delivery of health services (they write the orders that begin a series of interlinking care processes involving many other providers, and drive medical costs and reimbursements), they often have little or no control over the delivery of those services. Governing boards should understand that it is the *institution* that will receive the report card of the future (not just the physician) and that governing boards hold the responsibility for ensuring that resources exist to provide care and to measure performance.

Performance measure
A measure, such as a standard or indicator, used to assess the performance of a process or function of any organization.

14. *Darling v Charleston Community Memorial Hospital*, 33 Ill2d 326, 211 NE2d 253 (1965), cert denied, 383 US946 (1966).

At a minimum, leaders should be able to respond to fundamental questions of quality, cost and customer satisfaction. Who are our customers? Are we organized around their needs? Are the right people doing the right things (at the right cost)? Answers to these questions help to establish priorities for organizational direction.[15]

Key leadership points of quality management are:

- Leadership is the driving force in creating and supporting the way people think about what they do.
- Leadership's influence permeates throughout the entire organization – every person, every function.
- Leadership establishes the basis for procedures and focuses on customer visibility.
- Leadership must insist on and reward excellence.
- Leadership's role must be genuine and visible, with active participation in establishing, achieving, and rewarding the realization of quality objectives.

Strong leadership will be needed to drive a quality agenda in a dialysis unit. Dialysis unit leaders (especially nursing, medical, administrative) should be familiar with methods for measuring performance, and provide guidance in selecting priorities for improvement projects. Additionally, leaders should provide resources and training to staff to enable *them* to carry out the more intensive work of data collection and detailed process analysis and improvement.

15. *Guide to Quality Management.* 5th ed. Skokie, IL: NAHQ; 1995.

Assemble Project Team and Assign Team Roles

The activities in Step One are geared to preparing for the work ahead. They include assembling a project team, naming a team leader, introducing team members to team roles and responsibilities, and team training.

Putting together an effective team is an essential element in the quality process. Teams are groups of employees. The goal of employee involvement is to give people increased influence over their work. Quality teams meet on a regular basis to identify and solve work-related problems.[16]

Quality Teams are Different from Patient Care Teams

While both suggest the need for the participation of *multidisciplinary members*, the work of the care team is directed toward review of individual patient care. In contrast, the quality improvement team will be looking at the health care delivery system and processes that are in place to provide care to populations of patients.

Quality team membership is dictated by the nature of the process to be improved. People who work closely with the process or groups likely to be affected by the process should have representative members. Membership will often cross divisional boundaries to accomplish this representation and often includes people of different ranks, professions, shifts or work areas. Groups with more than 15 members are considered difficult to work with; a better group size is five to ten members. The Facility Project Team should begin with the following:

- The facility medical director or another designated physician with knowledge of the *basic process* (or practice protocol) the facility uses in managing anemia
- The Director of Nursing Services
- The Dialysis Unit Administrator

16. Brassard M, Ritter D. *The Team Memory Jogger: A Pocket Guide for Team Members*. Methuen, MA: GOAL/QPC; 1995.

Engaging the participation of leaders at the beginning of the project is essential. Additional staff should be anticipated and added to the team during the formative stages in preparation for detailed process investigation and data collection. To investigate a process and attempt change that will result in improvement (better outcomes), it is *vital* that those staff selected be familiar with and work in the process being examined. In other words, select team members from staff *who actually do the work*! If time constraints are a problem in assembling the team, consider starting with the three critical members (the head nurse, medical director, and administrator) and expand membership as the core team becomes more familiar with the project.

Other physicians whose patients are cared for in the dialysis center should be invited to join the team or to review team progress from time to time. They will provide other perspectives and can help to interpret data. This is especially important in facilities that do not utilize general clinical protocols for anemia management.

Select a Team Leader

Each group must function in an administrative framework that supports the team's activities, services, and resources, gives authority to the team's work and gives the team its mission. The team leader will be required to bring together all the skills and resources needed to carry out a project. He or she thus serves as both a task manager and a liaison between administration, clinicians and clinical staff. The team leader should possess the general competencies of a *change agent* in communicating, problem solving, innovating, and championing the larger agenda. Of particular importance are interpersonal communication skills.

Frequently, the team leader facilitates meetings. The facilitation duties, however, can be taken by anyone on the team and may be traded several times during the course of a project or even during a single meeting. In some organizations the team leader and the facilitator are different people/roles.[17] The facilitator is objective, has no ownership of the process and can move the team along.

17. Scholtes P. *The Team Handbook*. Madison, WI: Joiner Assoc Inc; 1989.

Duties of facilitation include:

- Moving the discussion along in the allotted time frames.
- Pulling the group together if the discussion fragments into multiple conversations.
- Encouraging or pulling input from quiet members.
- Preventing domination by one group member.
- Checking for consensus on group decisions.

The management duties of a team leader are particularly challenging since the team leader will have many of the responsibilities of a manager, but may not have the corresponding authority over project team members. (For example, a nurse leading a team of doctors, pharmacists, nutritionists, etc.) Many times the role of team leader may be assumed by a physician when a clinical process (such as the management of anemia) is being investigated. This is entirely appropriate and often preferable since the physician is the initial *owner* of the process. Later, as process investigation progresses, the assignment of leader may change as other subprocesses are explored.

All team roles and responsibilities should be carefully explored and understood. Several references for *teams and teaming* are listed at the conclusion of this Guide and all participants are strongly encouraged to acquire one of the teaming handbooks as a reference for the staff. Additionally, there are increasing numbers of resources available in local communities for learning/practicing facilitation skills. Many hospitals and universities now have *quality* departments staffed by quality professionals who are often willing to provide guidance.

Why is teaming so important? Those closest to the process know where the problems lie and hold in their grasp the potential to fix them. If managed correctly, teams save time, money, and resources by giving those who perform the work the challenge of improving care.

◆ Review Purpose of Anemia Project and Potential Impact

The Anemia Project is a model for translating HCFA (customer) expectations that the care delivered in dialysis facilities is consistent with current professional knowledge. This requires agreement on what constitutes current practice (i.e., practice protocols or guidelines), an approach to measuring current performance (data systems), and a clinical team to perform the more intrusive work of process improvement.

Practice guidelines
Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions. (AHCPR, 1992)

What are we trying to accomplish?

- *Monitor quality* through population-based data analysis.
- *Improve quality* by using performance data to identify significant areas of variation in practice and direct improvement activities.
- *Build CQI capacity within the provider community* by promoting the application of CQI tools and techniques in the dialysis setting.

Continuous quality improvement (CQI)
A structured organizational process for involving personnel in planning and executing a continuous stream of improvements in systems in order to provide quality health care that meets or exceeds customer expectations.

The Anemia Project provides dialysis teams with a treatment algorithm (*Fig. #10*, Step Three), comparative performance data (ESRD Anemia Profile Report), and this Guide for process improvement. The Anemia Project is designed to *jump start* quality improvement efforts within dialysis programs, recognizing that many dialysis facilities do not currently have expertise nor resources with which to engage in quality measurement and management on their own.

Establishing Priorities for Improvement – Outcomes Assessment

There are a number of improvement goals for quality improvement teams in health care organizations to consider. Many are directly related to a patient's health, such as with the management of anemia; others are not. For example[9]:

- Health related goals
  - Avoid adverse outcomes such as bleeding, hypertension, clotting of vascular access. This type of defensive goal has been the focus of traditional quality assurance programs.
  - Improve the patient's physiologic status: increase hematocrit, increase iron stores.
  - Reduce the patient's signs and symptoms: episodes of shortness of breath, chest pain, generalized weakness.
  - Improve the patient's functional status: increased exercise tolerance, increased energy, ability to work, ability to conduct activities of daily living.
- Other goals of health care are not health related:
  - Achieve patient satisfaction: for example, patient preferences for route of drug administration, choice of dialysis setting, relationships between patients and caregivers.
  - Minimize the cost of care: assuring adequate dialysis and iron stores to potentially reduce the required dose of Epoetin alfa; reduce or eliminate blood transfusions.
  - Maximize revenues: comparisons of routes of administration, volume purchases, analyze loss of revenue associated with hospitalizations, cost/benefit ratios of preventive approaches to care.

Among the most important reasons for establishing an outcomes assessment initiative in a dialysis facility are to:

- Describe, in quantitative terms, the impact of routinely delivered care on patients' lives.
- Establish a more accurate and reliable basis for clinical decision making by clinicians and patients.
- Evaluate the effectiveness of care and identify opportunities for improvement.

9. *A Guide To Establishing Programs For Assessing Outcomes In Clinical Settings*. Oakbrook Terrace, IL: JCAHO Joint Commission: 1994.

Enhancing patients' quality of life is the primary incentive; marketing or administrative motivation should be secondary.

Dialysis organizations should be cognizant of the increasing trend in health care to monitor outcomes of key processes of care. Dialysis providers should anticipate this trend and begin to establish a *facility-based* outcomes assessment program. Outcomes chosen for review should be *customer-driven* and preferably negotiated between purchasers, providers, and recipients of service.

Patients, providers, and government representatives were all involved in selecting anemia as an outcome of interest. The Anemia Project addresses the needs of the dialysis center's two primary customers – the patient and HCFA – and meets the following specific selection criteria[12]:

- A condition that is frequent in the Medicare ESRD population.
- Guidelines for care are well-defined and widely accepted.
- Methods are available to measure outcomes and risk factors.
- Conforming with guidelines does not require large changes in available skills or resources.
- There is a substantial, clinically important difference between guidelines and actual practice.
- There is substantial variation in outcomes.

Anticipate Impact

The Anemia Project may be a significant quality improvement effort for some and may impact on several facility operations. For example, time will be needed for meetings and data abstraction. The team should discuss the importance of the project and plan for necessary resources in advance. However, it should not be the only quality improvement effort. Most dialysis facilities will have other important quality projects to consider as well as the quality improvement project. It will be important to balance the needs of external customers (payers and patients) with internal customer needs (staff satisfaction, education and training, intradepartmental suppliers, monitoring other health care goals).

Outcomes assessment
Health outcomes go beyond the traditional measures of mortality and complications to include the patient's physiology, signs and symptoms, functional status, and well-being. An outcomes assessment effort focuses on measuring these constructs, monitoring patients over time, and giving clinicians feedback about results to help them optimize the process of care. (JCAHO, 1994)

Criteria
Expected level(s) of achievement, or specifications against which performance can be assessed.

Variation
The differences in results obtained in measuring the same phenomenon more than once. The sources of variation in a process over time can be grouped into two major classes: common causes and special causes.

12. Eggers PW, Greer J, Jencks S. The use of Health Care Financing Administration data for the development of a quality improvement project on the treatment of anemia. *Am J Kid Dis.* 1994;24:247-254.

Process improvement
A methodology utilized to make improvements to a process through the use of continuous quality improvement methods.

◆ Choose Method for Process Improvement

Using a systematic approach, such as the one outlined in this Guide, to solve problems can help teams (and individuals as well) avoid some of the common pitfalls of ineffective problem solving which are listed below[18]:

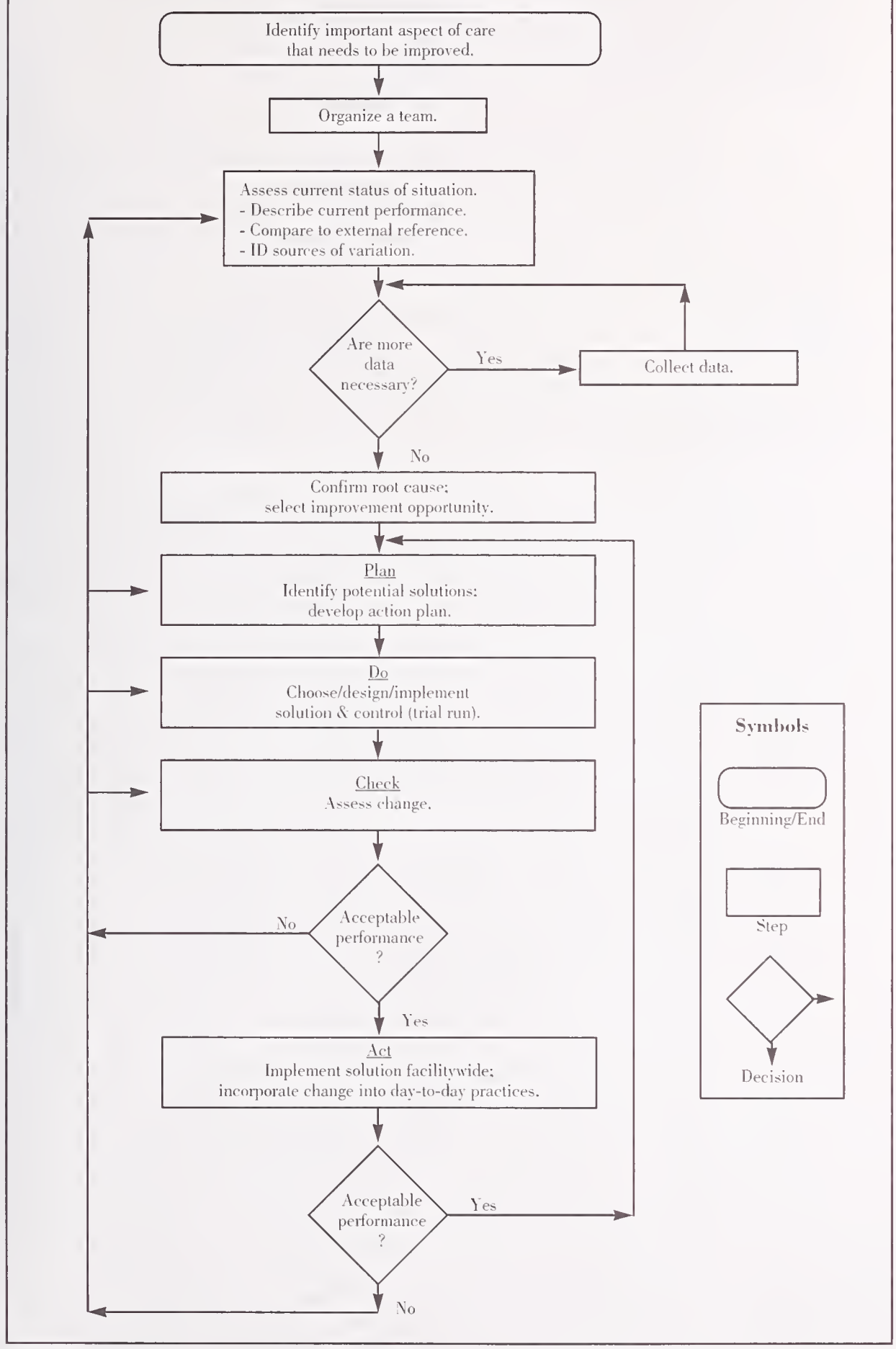
- Jumping to a conclusion before effectively analyzing all aspects of the problem.
- Failing to gather critical data, either about the problem or proposed solutions.
- Tackling problems that are beyond the control or influence of group members.
- Working on problems that are too general, too large, or not well-defined.
- Failing to develop adequate rationale for a solution.
- Failing to involve critical people – especially those outside the group – when looking for solutions.
- Failing to plan adequately how to implement and evaluate the recommended solution.

Systematic improvement generally implies identifying an opportunity to improve, testing the strategy for change, assessing data to determine if performance improved, and implementing improvement action systemwide. There are many approaches to systematic improvement which include: the JCAHO's 10-Step Process; PDCA Cycle, developed by Walter A. Shewart in the 1920s; FOCUS-PDCA, developed by Hospital Corporation of America; FADE, developed by Organizational Dynamics, Inc.; and IMPROVE, developed by Ernst and Young.

The *RoadMap for Improvement* introduced in this Guide is an adaptation of FOCUS-PDCA, A Process Improvement Strategy, developed by the Hospital Corporation of America (HCA). The HCA added a strategy called FOCUS to the legendary Shewart cycle of *Plan, Do, Check, and Act* (PDCA.) FOCUS is an acronym for *Find, Organize, Clarify, Understand, and Select*. In general, FOCUS helps to narrow attention to discrete opportunities for improvement. The PDCA Cycle allows the team to pursue that opportunity (Fig. #2).

18. *NYS Process Training Guide*. Albany, NY: State of New York, Dept of Health.

Fig. 2 **FLOW CHART OF FOCUS-PDCA PROCESS**



This approach is recommended for three reasons. First, it delineates activities necessary to measure performance. Second, it has been tested and shown to be acceptable during the Anemia Project pilot phase. Third, using this approach will facilitate communication among Network staff and your project team, enabling Network staff to provide you with assistance more efficiently.

The time intervals between the *improvement* steps are flexible. Movement between steps is dependent on the accomplishment of the tasks within each step, and each step may require one or many team meetings. It is important to establish an overall time line for the project at the beginning (i.e., 3-6 months). Teams should be required to report progress to their own management by the end of the initial time limit and, if needed, negotiate for additional time – and resources. Figure 3 shows a time line established by a project team during the pilot phase of the Anemia Project.

Fig. 3 **TIMELINE – EXAMPLE FROM PILOT PHASE OF ANEMIA PROJECT**

ROADMAP & Timeline for Improvement

QUALITY PLANNING ----------> QUALITY MEASUREMENT & ASSESSMENT ----------> QUALITY IMPROVEMENT

Pre-Pilot Phase	Pilot Phase ---------->						
QI Methodology	Identify Process for Improvement	Clarify Current Knowledge of Process	Understand Causes of Variation	Search for Root Causes	Implement Improvement Trial	Evaluate	Report
Timeline———>	Aug-Sep '94	Sep-Oct 15 '94	Oct-Nov 15 '94	Nov '94	Dec '94	Jan '95	Feb '95
ROADMAP for Improvement	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7
• Develop tools • Train NW coaches • Select pilot facilities	• Assemble team • Introduce project • CQI training and background	• Examine HCFA claims data • Write opportunity statement • Collect current data • Flow chart process • Examine anemia algorithm	• Analyze data • Identify causes of variation • Measure causes	• Analyze data • Identify root causes • Link cause to outcome • Select area for improvement • Plan improvement trial	• Implement trial • Collect data	• Evaluate trial	• Implement change ...or... • Find new cause • Report findings
..... PLAN					..... DO	..... CHECK	..... ACT .....

◆ Identify Team Training Needs and Institute as Needed

The tools and techniques of quality improvement may not be familiar to many dialysis unit personnel. The scientific process embedded in performance measurement may seem familiar; however, the application of many of the statistical tools and the group problem solving techniques are not. An initial investment in training staff in the use of CQI tools and techniques will pay off later in time saved during process investigation, as well as in improved participation of all team members.

◆ Achieve Consensus

A Word About Team Consensus

Although consensus is commonly used to mean complete or unanimous agreement, its precise meaning is general agreement. A consensus is reached when all members of a team are willing to accept a decision. Even though a decision may not necessarily be an individual's first choice, he or she considers it a workable approach and in the best interest of the group.

Reaching team consensus requires *eliciting all points of view*, then reaching a decision. Effective consensus building requires that each team member be able to say:

- I believe that you understand my point of view.
- I believe that I understand your point of view.
- Whether or not I prefer this decision, I will support it because it was reached openly and fairly.

HOW TO'S

Preparing the team or group for clinical process analysis is critically important. This Guide contains basic information to assist providers in taking the first step. It will be necessary for *all team members* to read through the entire Guide before continuing. Supplemental reading is strongly encouraged and workgroup recommendations can be found at the end of the Guide.

Sample Approach for Conducting Activities in Step One

- Meet regularly.
  Meetings should take place on a frequent and regular basis (i.e., once a week) until the work of the project allows for fewer meetings. Establish an agenda of time, dates, and meeting purpose. Allow at least an hour for each meeting.
- Distribute support materials in advance.
  The Guide requires several hours to read. Multiple copies of the Guide are being distributed to facilitate greater distribution of support materials. You are encouraged to make additional copies so that each of your team members is equipped with the necessary information and can read the materials at home or at work.
- Encourage discussion of main project concepts among team members.
  Why was this process chosen for improvement?
- Clarify any points of confusion.
  Review project goals and objectives as a group. All team members must understand what they are being asked to do. Solicit reactions or questions from all team members. Clarify all areas of confusion. If necessary, call the Network Quality Director for answers to unresolved questions.
- Review basic concepts associated with *teams and teaming.*
  Go to the Teams, Tools, and Techniques (The 3Ts) section of this Guide. Discuss the concepts associated with the use of the *3Ts*, the purpose of teams, team membership, roles and responsibilities, and why certain tools and techniques are used at particular times.

- Assign roles, review responsibilities and establish project time lines. Project teams may combine and/or change roles as the project progresses.

  Members – knowledgeable about the process being studied

  Team Leader – owner of the process

  Coordinator – team manager; coordinates and schedules meetings

  Recorder – maintains team progress records

  Timekeeper – helps team manage time during meetings

  If available:

  Facilitator – (Quality Coach) keeps the team focused on quality improvement process.

  Consultant – provides insight and/or advice to group based on area of expertise.

- Identify a format for reporting team progress. The storyboard method is optional but recommended.
- Review the How To's for using CQI tools and techniques. (See the Tools and Techniques Chapter.) Practice techniques using a subject familiar to all team members.

CHECKLIST FOR STEP ONE*

* Template for this page available in Appendix.

At the end of Step One, the team should have accomplished the following activities and reached consensus on the answers to the following questions:

- ☑ Assembled a team and conducted orientation meetings.
- ☑ Discussed team roles and reviewed team guidelines.
- ☑ Identified a team leader.
- ☑ Assigned team roles and responsibilities.
- ☑ Identified a format for reporting team progress.

  Has the group discussed team roles and reviewed team guidelines to the satisfaction of all team members?
- ☑ Discussed the aim of the project.
- ☑ Selected a quality improvement methodology.

  Does everyone on the team share a common understanding of the HCQIP project?
- ☑ Identified customers of the process improvement project: HCFA and patients.
- ☑ Identified and discussed customer expectations.
  - Measure organizational performance with median facility hematocrits.
  - Improve the anemia status of dialysis patients.

  Does everyone in the group understand why this aspect of care was chosen for process improvement?
- ☑ Instituted team training.
  - Read the Guide.
  - Practice team behavioral techniques.
  - Practice tools development.
  - Encouraged supplemental reading.

  Does everyone in the group have a common understanding of the recommended tools and techniques for process investigation and improvement?

NOTES

STEP THREE

STEP FOUR

STEP FIVE

STEP SIX

OBJECTIVE

Clarify Current Knowledge of Process Performance and Write an Opportunity Statement

ACTIVITIES

- Review and discuss ESRD Anemia Profile Report from HCFA.
- Identify customer expectations.
- Plan and collect current baseline data.
- Manage the data.
- Produce data displays for team analysis.
- Write an opportunity statement.
- Begin recording team progress (storyboard/storybook).

DISCUSSION POINTS

Review Profile Report

The overall goals of Step Two are to establish baseline measures of facility performance (which will be monitored throughout the project) and to write an *opportunity statement* for the CQI project. Team members may use data contained in their facility's ESRD Anemia Profile Report to begin to address the questions of *How are we doing?* and *Compared to what?* However, the Profile Report represents a snapshot of past performance. New data should be collected and reviewed by the team to confirm current performance before writing an opportunity statement and proceeding to Step Three.

There are three components to a systematic approach to improving quality: performance measurement, assessment and improvement. Measurement is the first step. All true measurement is comparative, and comparisons are helpful both within an organization over time and between organizations.

Clinical measures
Data reported by the practitioner for specific patient care services.

The ESRD Network has provided your facility with comparative data derived from *clinical measures* reported to HCFA on the erythropoietin (EPO) billing claims. These data, entitled the ESRD *Anemia Profile Report*, will arrive under separate cover before the receipt of this Guide. The facility's median (midpoint) hematocrit is the outcome or performance measure for the management of anemia. The facility data are broken down further to describe the percent of patients with HCTs < 25%, < 28%, and < 31%. A sample Profile Report is included on the next page.

Fig. 4

ESRD ANEMIA PROFILE REPORT

For Calendar Quarters 3/94 - 2/95

Facility Provider Number: 000000
Facility Name: Dialysis Unit

Facility State: 00
ESRD Network: 00

Qtr 3/94

Parameters	Natl	Net	State	Unit
Median HCT	31.00	31.83	31.85	32.60
Median EPO	4000	4000	4077	5179
% HCT < 25	5.16	2.82	3.27	4.23
% HCT < 28	18.48	11.09	12.45	11.27
% HCT < 31	48.54	37.80	37.51	29.58
Number of Patients	128,526	5,246	1,253	71

Qtr 4/94

Parameters	Natl	Net	State	Unit
Median HCT	31.20	32.00	31.90	32.88
Median EPO	4000	4000	4333	5970
% HCT < 25	5.02	2.71	3.58	4.29
% HCT < 28	17.81	10.22	13.05	8.57
% HCT < 31	46.43	35.38	39.78	31.43
Number of Patients	129,034	5,159	1,257	70

Qtr 1/95

Parameters	Natl	Net	State	Unit
Median HCT	31.33	32.03	32.00	35.23
Median EPO	4000	4000	4222	6000
% HCT < 25	4.76	2.34	3.08	4.05
% HCT < 28	17.00	9.46	12.71	13.51
% HCT < 31	44.70	34.57	37.49	28.38
Number of Patients	129,807	5,167	1,235	74

Qtr 2/95

Parameters	Natl	Net	State	Unit
Median HCT	31.67	32.33	32.14	34.60
Median EPO	4115	4000	4152	5595
% HCT < 25	4.12	2.18	2.03	2.86
% HCT < 28	15.02	8.84	11.25	10.00
% HCT < 31	41.27	30.77	34.69	21.43
Number of Patients	127.780	5,138	1.280	70

Data Source: HCFA Administrative Records

The Profile Report also provides a *comparison* of your facility's performance with other dialysis facilities. The data are calculated for the nation, region (state and Network) and individual facility by calendar quarter.

As discussed in this Guide, renal community *assessment* of the EPO claims data has confirmed that there are compelling reasons for all providers to examine the management of anemia in their facilities and to perform the more intensive and intrusive work of *improving care*.

Opportunities to improve exist for all. Facilities that have patients with low hematocrits will probably quickly see *increasing median facility hematocrits* as their opportunity for improvement; others may wish to identify an opportunity to improve from within a subset of patients such as *nonresponders* or those patients below 28%. And those providers with higher median hematocrits can serve a vital role in describing their approach to anemia management which is producing better outcomes.

Using Comparative Data

What quality information is reported about an institution is naturally of concern to all. Providers want to be judged fairly, payers want information that will reflect efficiency and appropriateness of care, and patients want assurance that their care is *good*.

All data reports should be examined carefully. Team members should understand the source and limitations of the data contained in the Anemia Profile Report– that these performance measures (hematocrits from three months prior) provide a description of the past. A full discussion of the sampling techniques is provided with the report.

The advantages of using HCFA EPO claims data to stimulate improvement are:

- Completeness. The majority of chronic dialysis patients are covered by Medicare and the provider must submit bills in order to receive reimbursement for services provided.
- The data are already computerized.
- The data can be used to provide national, Network and state comparison values.
- The data demonstrate regional variation in outcomes.

Some of the disadvantages in using HCFA EPO claims data are:

- Data can be missing.
- Data can be delayed in processing and, therefore, are neither current nor complete.
- Only data for EPO billed to Medicare are included.

Despite its limitations, the data are a credible and important source of information for performance measurement. Whereas the data can be examined on a national or regional level to identify trends and regional variation in outcomes, only individual facilities can examine and improve the processes that produce those outcomes. Questions concerning the data may be referred to your Network office for clarification.

◆ Identify Customer Expectations

Identifying and meeting customer expectations are integral to quality management concepts. HCFA, the primary customer of this project, wants assurance that the management of anemia in dialysis patients is being performed effectively – *the right treatment administered the right way*. Is treatment being driven by the use of current science-based practice parameters (the right treatment)? If so, is the treatment being carried out consistently by a correct and efficient process (the right way)?

The team should consider, as HCFA has, this quality question: If EPO (which is available to most dialysis patients) can successfully correct anemia to hematocrits within a range of 31%-36%, why are almost half of the dialysis patients currently treated with the drug demonstrating hematocrits below 31%? The HCFA EPO claims data profiles present unexpected and undesired findings regarding outcomes of anemia management. This is the driving force behind this project. HCFA's expectation for the Anemia Project is, simply stated, to measurably improve the management of anemia for dialysis patients.

◆ Plan and Collect Current Baseline Data

Dialysis units are being encouraged toward and assisted in the development of internal *outcomes assessment* programs. Throughout this Guide the term outcomes assessment refers collectively to measurement, monitoring and feedback (providing clinicians with data and helping them to interpret the data as they analyze and modify the care process). The Anemia Project is a first attempt at linking national outcomes assessment data to internal process improvement and will provide valuable experiences for all future quality improvement efforts.

After examination of the Anemia Profile Report has been completed, the team's first data collection activity will be to collect a current, more inclusive, baseline data set from the facility's own data sources. The project team should be clear on what data or *indicators* need to be collected. The team will need to develop measurement instruments and establish a logistical protocol for data collection. The purpose of data collection at this point is to establish a baseline data set which describes current performance for use in writing an opportunity statement.

Indicator
A key quality characteristic used to measure, over time, the performance of functions, processes, and outcomes of an organization.

The new data sample to be collected for the Anemia Project should consist of 100% of the facility patients, and should indicate whether or not the patients are on EPO. Facilities wishing to associate the national data set with the current facility data will need to use sampling techniques similar to those used by HCFA in drawing the facility-specific sample. (For more information, refer to the narrative portion of the ESRD Anemia Profile Report.) It is not necessary, however, to mirror the HCFA-produced data set in order to conduct a successful improvement project.

Checksheets (*Fig. #5*) are *measurement instruments* that are used when there is a need to gather data based on sample observations. Checksheets are easy-to-understand forms used to answer questions. For example, *What is the patient's current hematocrit? Is the patient on EPO?* Data from checksheets start the process of translating *opinions* into *facts.*

Fig. 5 **CHECKSHEET - BASIC***

Checksheet for
Baseline Hematocrit Data Collection

Patient ID	Check if on EPO	_____ month HCT	_____ month HCT	_____ month HCT
Mean for all patients				
Mean for patients on EPO				
Mean for patients not on EPO				

* Template available in Appendix.

1. List all patients to be studied in first column by name or reference number.
2. Team decides which lab method will be used for monitoring hematocrits (Coulter vs. spun). It is a good idea to track the method used for adjusting EPO doses.
3. Collect data from patient records or summary lab reports. (Listing and recalculating the hematocrits is not necessary if the lab already produces a mean or median HCT for the unit.)
4. Team decides to use mean or median.
5. If computer resources are available, patient data can be entered into a spreadsheet software program and the computer will calculate the mean or median. If data management is to be done manually, the checksheet above may serve as a generic form.

Multiple sources of data exist in the dialysis unit, and the team should identify those that currently exist (e.g., the facility's clinical laboratory service, billing data). Most laboratories have the capability to produce facility-specific data profiles such as facility median hematocrits, percent of patients below 28%, etc.

Network staff will be available to provide assistance to project teams in developing timesaving ideas for data collection, protocols, and instruments.

Data collection must be performed by informed staff. Data abstractors should be knowledgeable and confident in the use of the data collection forms (checksheets), and informed of all sources of information. If more than one individual is involved in collecting data, all abstractors must be consistent in their approach to the collection process. The answers to such questions as *which hematocrit to use* (spun vs. Coulter, pre- or posttreatment, first of the month, or other) should be clearly described in *instructions* to the abstractor.

◆ Manage the Data

The subject of data management is important to the present activities of the project team and to future quality measurement and assessment activities. Managing data includes collecting the data and entering it into a database, maintaining quality control over the data and storing the data. Computer access and capability are not essential but will definitely be of benefit to teams involved with larger patient populations.

The team should consider how to manage, display, and store data for subsequent use. If a computer is being used, make sure those designing the file and entering data are familiar with the software and with the project team's needs.

◆ Produce Data Displays for Team Analysis

Managing data includes transforming data into information. *Data* can be multiple pages of numbers which are meaningless in that format and exhausting for the team to review. Converting data into graphs provides a quick and clear view so that information is readily communicated to the team and others. For example, consider the transformation of pages of vital signs data on to a one-page graph referred to as the TPR chart.

The TPR graph is also known as a **Run Chart** and is utilized to monitor a variable over time. Figure 6 shows a run chart of the percent of patients with hematocrits below 30% profiled over time. Displayed graphically, any significant variation in the data can be seen. Variation may suggest unusual process issues which require investigation of the causes. The addition of statistically determined limits to a run chart converts it to a **Control Chart** (*Fig. #7*), which is an advanced quality management tool.

It is highly recommended that facilities initiate a run chart with the new average or median hematocrit based on a 100% facility sample.

Fig. 6 **RUN CHART**

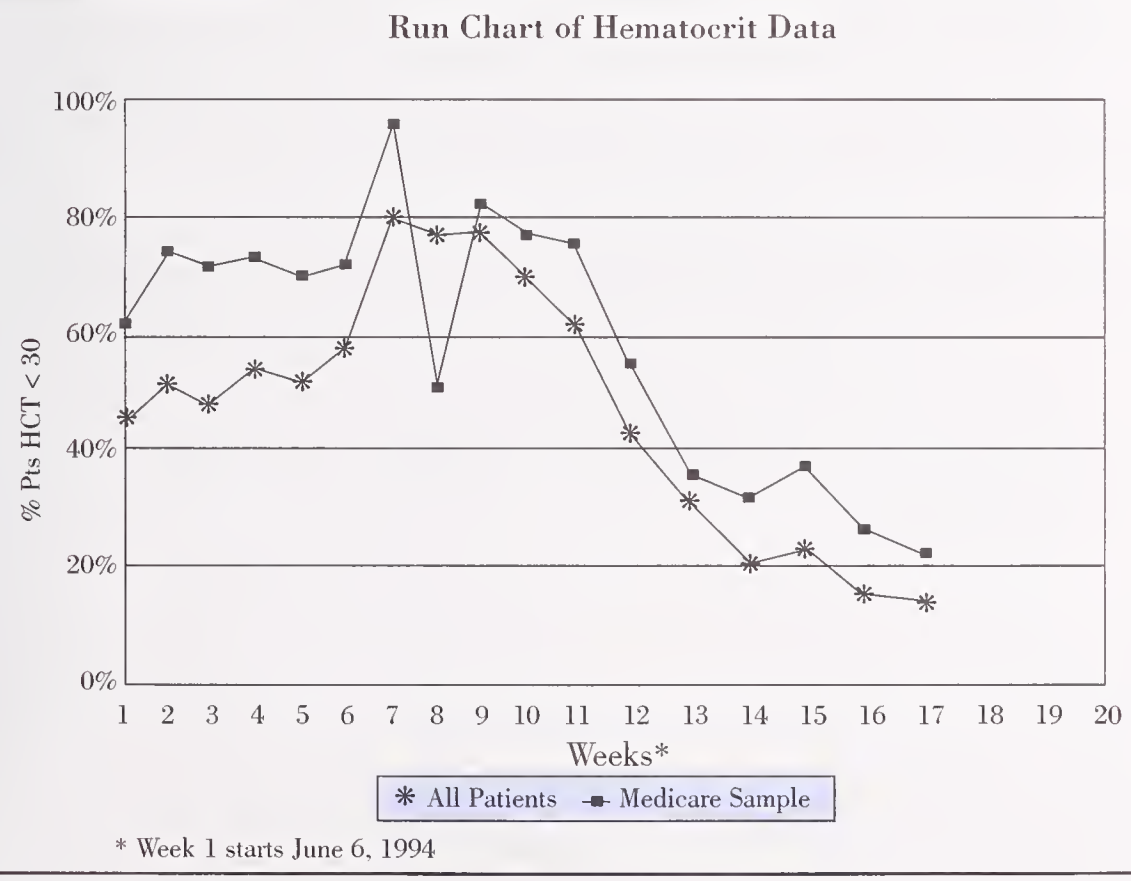
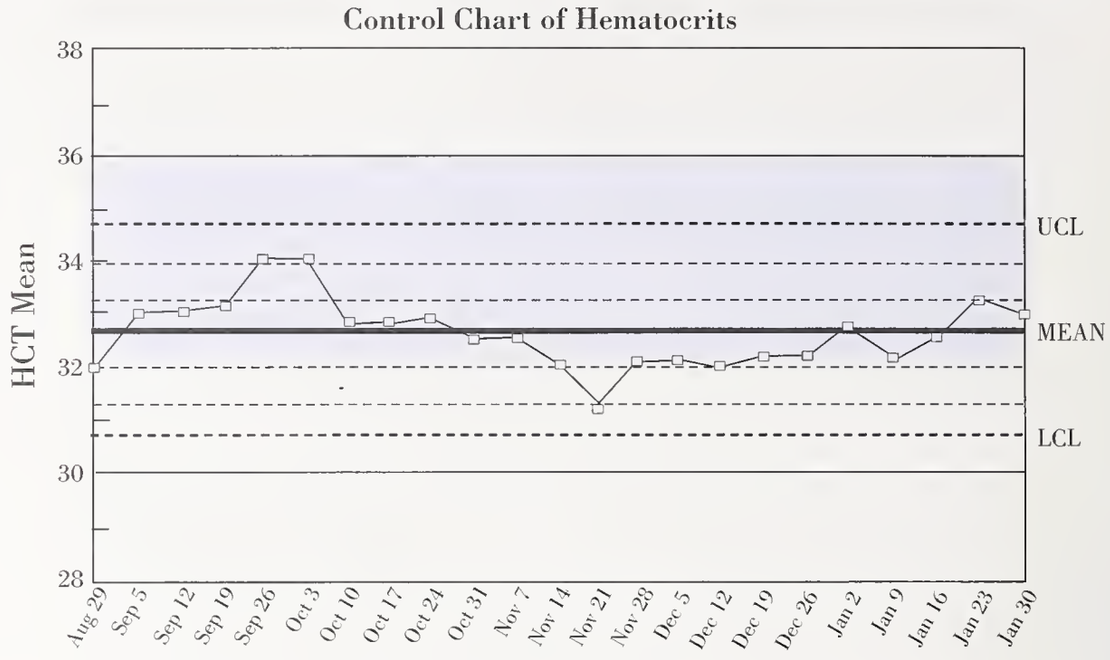


Fig. 7 **CONTROL CHART**



Upper & Lower Control Limits (UCL & LCL) were set at ± 3 Standard Deviations
Shaded Area is Treatment Goal Range of 32 - 36

Write an Opportunity Statement

When current facility data are ready for analysis, the team must consider the following questions in writing an opportunity statement: *Where are we? What are our rates? Where are others? Where should we be?*

The opportunity statement should describe the situation that you want to influence as it currently exists, and as objectively as possible. For example: *Thirteen percent of the patients in our facility have hematocrits below 30%.* To counter-balance the *as is* statement of the current situation, you will also specify a *desired state* – a description of the condition you want to achieve by solving the problem.

Opportunity statements must be free of either causes or solutions. It is premature to incorporate causes and solutions into the opportunity statement because additional data must be collected and analyzed before a root cause and its solution are apparent.

Fig. 8 **OPPORTUNITY STATEMENT**

An improvement opportunity exists with the treatment of anemia beginning with the recognition that action is needed (a trigger/threshold) and ending with a stable hematocrit between 32%-36%. The current process causes variation in hematocrits with 13% of patients below 30%. Improvement should result in all patients demonstrating a hematocrit in the 32%-36% range.

◆ Begin Recording Team Progress (Storyboard/Storybook)

Tracking team activities and progress is essential.Team members should select the method that is comfortable and easily understood by all members. Many quality teams use a storyboard and/or a storybook format *(Fig. #9)*. A storyboard is a visual display of the data, analyses and decision making that took place during the quality improvement project. It may contain all the graphs, charts, diagrams, and other display methods utilized to describe the project text.

The storybook is written in more depth than the storyboard. Typically it contains the quality improvement team agendas, meeting records, data, and other materials held by the group, in addition to the graphics displayed on the storyboard.

Storyboard/Storybook
Tools used to record and display the team's progress. Storyboards vary in size and may be posted in staff lounges or other visible areas. Each phase is summarized, then updated. A more detailed version is called the storybook. It may include raw data and minutes from team meetings.

* Template available in Appendix

Fig. 9 **STORYBOARD***

Storyboard Format for Seven-Step Approach

Step One: Commit to Improve Care	Step Two: Clarify Knowledge of Process Performance and Identify Opportunity to Improve
Step Three: Analyze Process and Identify Sources of Variation	
Step Four: Search for Root Causes and Select an Area for Improvement	Step Five: Design and Implement Improvement Trial
Step Six: Evaluate Improvement Trial and Initiate Change	Step Seven: Communicate Results

HOW TO'S

- Make sure everyone on the team understands the facility's Anemia Profile Report – its advantages, disadvantages and its intended use in stimulating process investigation.
- Measure current performance and establish an ongoing procedure for monitoring the process under investigation.
- Clarify HCFA/Network expectations. Check with local Network staff as needed. Review information contained in the accompanying reference document and the Anemia Profile Report.
- Take time to plan your data collection. Your sample should reflect your needs. A baseline of 100% of the patients helps to visualize the *population.*
  - Agree on data to be collected and its intended use, and consider in advance how to display the data. (Does the team want to work with one data point, or does it prefer subsets of data? > 31%, < 28%, < 24%?)
- Access to a computer, though not essential, is recommended. A simple spreadsheet program will save a great deal of time. Ask your laboratory service for assistance.
  - Design a data collection tool (*Fig. #5*). Be sure to tap into the enthusiasm and expertise of *computer-literate* staff.
- The purpose of data displays is to assist the team in understanding. Supplemental reading on tools for quality analysis and displays is essential.
  - Display the data. Begin Run Chart(s) (*Fig. # 6 and 7*).
- Wait to write the opportunity statement until after the team has reviewed its current facility data. Then write an objective statement of the problem and the desired state.

* Template for this page available in Appendix.

CHECKLIST FOR STEP TWO*

At the end of Step Two the team should have accomplished the following activities and reached consensus on the answers to the following questions:

- ☑ Reviewed Anemia Profile Report.
- ☑ If needed, requested clarification of the data from the Network Office.

  Does everyone understand the HCFA comparative data?
- ☑ Planned and designed a current data sample and instruments for data collection.
- ☑ Assigned responsibility for data collection.
- ☑ Established a time frame for completion of the data collection.
- ☑ Instituted data collection.

  Does everyone agree that the new data accurately reflect current performance?
- ☑ Prepared data displays.
- ☑ Conducted meetings to review new data.

  Have we established an acceptable procedure and data format to plot data regularly (at least monthly)?
- ☑ Selected a format for reporting progress.

  Does everyone understand the progress reporting format?
- ☑ Written an opportunity statement.

  Does everyone agree that the opportunity statement is written in objective terms stating both the "as is" as well as the "desired state" of performance?

STEP THREE

STEP FOUR

STEP FIVE

STEP SIX

STEP SEVEN

OBJECTIVE

Describe and analyze the basic process and identify sources of variation (Process Analysis)

ACTIVITIES

- Understand the concept of variation.
- Conduct process analysis – describe the process.
- *Compare* the facility's process to external references (anemia algorithm, protocols and other external references such as practice guidelines, when available).
- Brainstorm for *potential sources of variation* (causes of low hematocrits).
- *Confirm* which sources are real (plan, collect and display data).
- Select one key source of variation for further investigation and action.
- *Continue monitoring* the process (using facility mean or median hematocrit) and update run chart.
- Continue progess report (storyboard/storybook).

DISCUSSION POINTS

◆ Understand the Concept of Variation.

Variation refers to any deviation from the expected. Are the parameters of the facility's process consistent with current community practice or the scientific literature? Are there differences between the facility's approach to anemia management and the external references consulted – such as the Anemia Clinical Algorithm (*Fig. #10*)? Team members must understand the process well enough to be able to analyze it and make distinctions between the way the process actually works and the way it is supposed to work.

Variation is caused by either *common causes* or *special causes* and can be seen readily when the output of a particular process is measured and displayed graphically on a **Run Chart** or **Control Chart**. (Hematocrit values, an outcome of anemia management, can be followed graphically on a run chart.) Variation is unavoidable, yet must be understood, controlled, and reduced to the extent possible. Variation reflecting weak performance frequently leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services.[19]

19. McLaughlin CP, Kaluzny AD. *Continuous Quality Improvement in Health Care: Theory, Implications and Applications.* Gaithersburg, MD: Aspen Pub.; 1994

Please fold open for fig. 10

Common cause variation is always present and is a type of variation inherent in all processes over time, affecting all outcomes and individuals. These variations are part of the process and can be reduced or removed only by making changes in the process. Often these changes are highly desirable and constitute the substrate of continuous improvement projects and efforts. Some sources of common cause variation include: the design of a process, choice of equipment, preventive maintenance of equipment, worn or outdated equipment, inadequate instruction or supervision of employees, failure to provide staff with information to assist them in improving performance and reducing variation.

Examples of common cause variation in the delivery of adequate hemodialysis might include: patients taken off early, staff failing to record time accurately, or required blood flow not maintained throughout the dialysis procedure. Examples of common cause variation affecting the management of anemia are illustrated on the **Fishbone Diagram** below. (*Fig. #11*)

* Template available in Appendix.

Fig. 11 **CAUSE-AND-EFFECT ANALYSIS (FISHBONE DIAGRAM)***

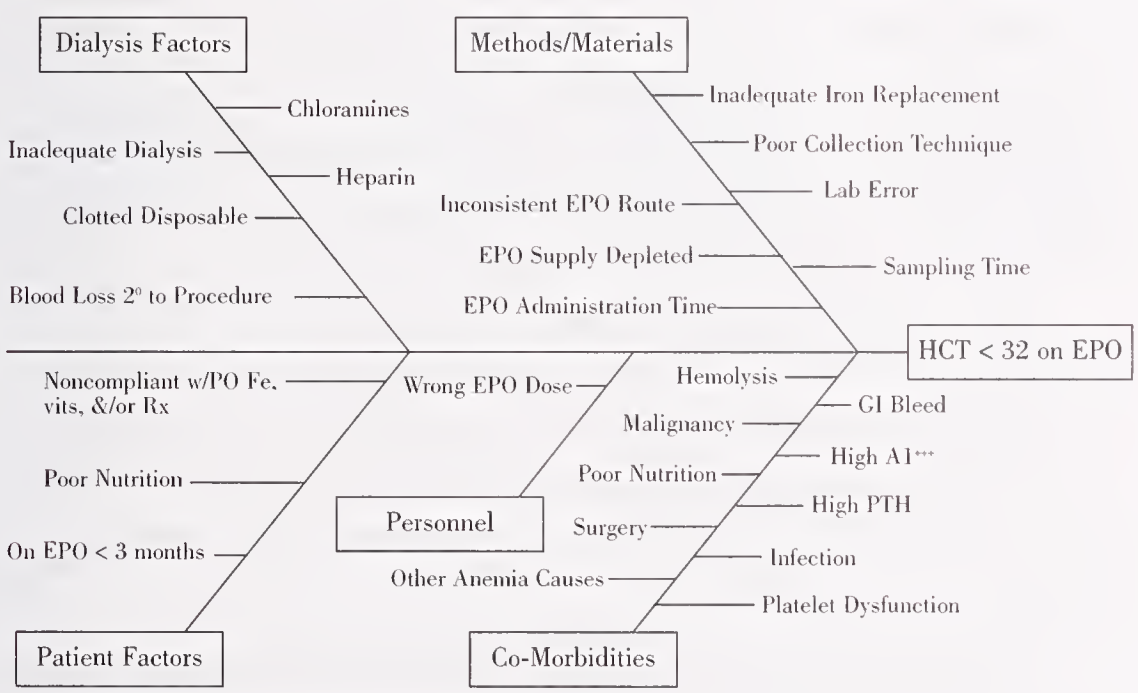
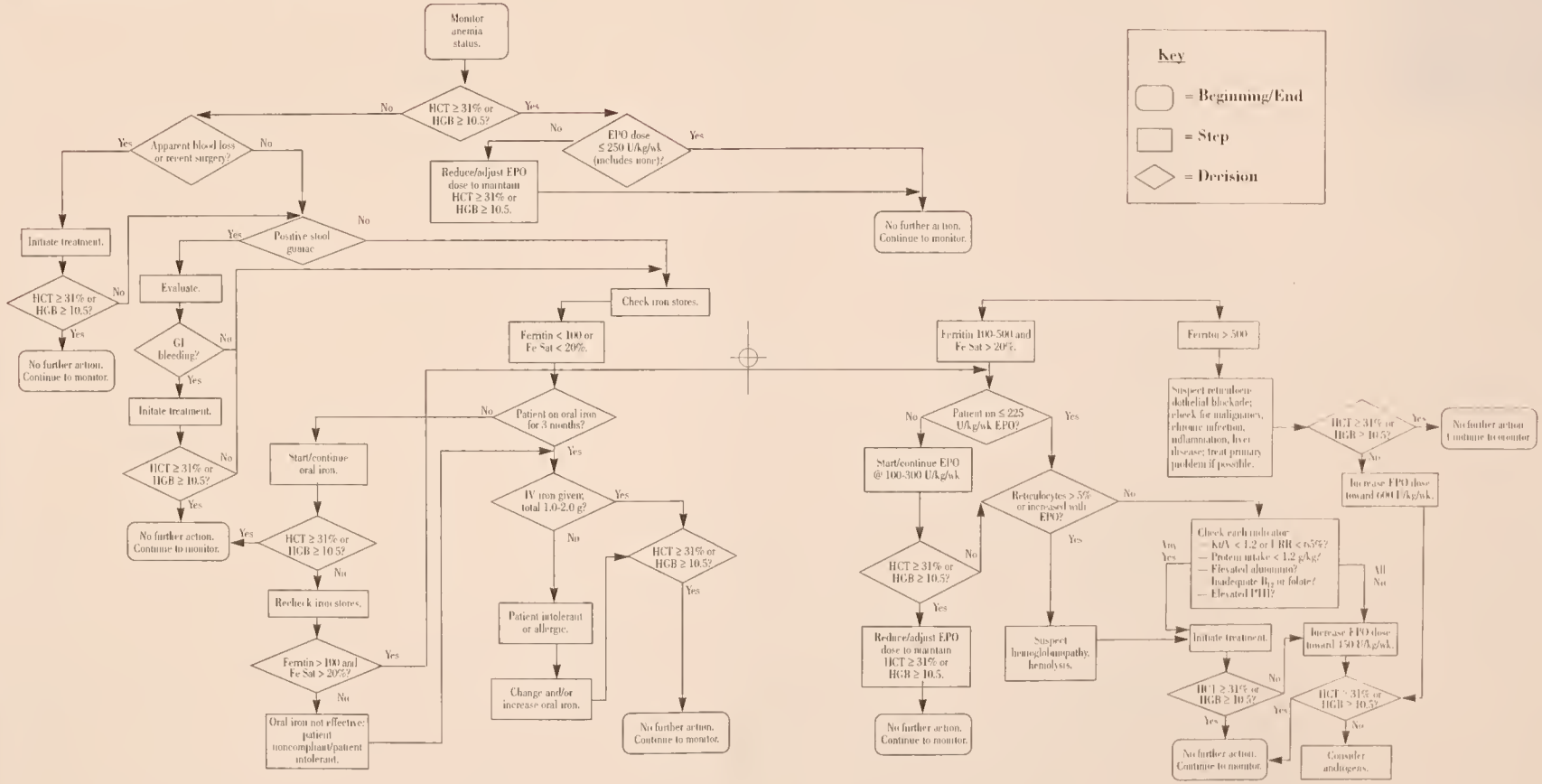


Fig. 10 **DETAILED FLOW CHART**

THE ESRD NATIONAL ANEMIA COOPERATIVE PROJECT:
Algorithm for the Treatment of Anemia in ESRD



Another type of variation, called *special cause*, is not inherently present in the process itself. Special cause variation arises from causes or circumstances that are not part of the process as designed. Special cause variation is intermittent and indicates that a process is unstable. Health-related examples might include an epidemic of infections or episodes of hemolysis. Ideally, once detected, special cause variation that results in undesirable outcomes must be eliminated immediately, leaving the process with only common cause variation.

There are special causes of variation in the management of anemia. However, a subgroup of patients (often referred to as outliers) whose hematocrits are below the facility's norm (such as a cluster of patients with sickle disease) do not constitute special cause variation. These patients will always be a part of the process by which anemia is managed and, therefore, must be accommodated. Further, this subgroup will probably be identified as a possible source of variation and data collected on the checksheet. However, **Pareto Analysis** will probably show this group to be among the *important many* rather than the *vital few*. Teams should resist the inclination to focus solely on these individual problematic subgroups.

◆ Conduct Process Analysis – Describe the Process

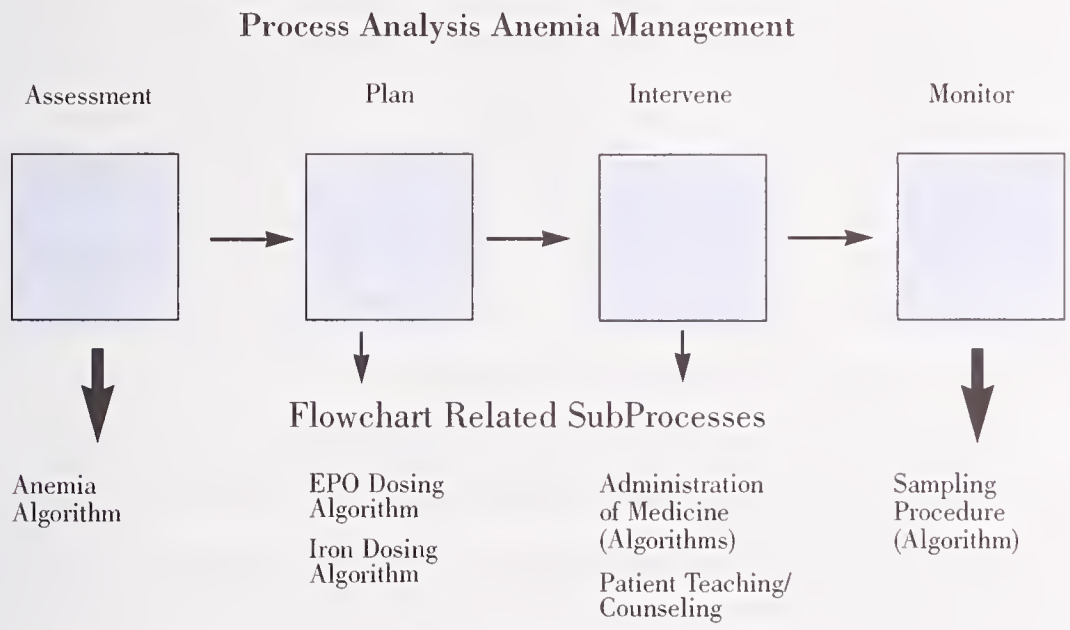
A process is a series of related tasks. For example, the process of hemodialysis consists of preparing the patient, initiating therapy, monitoring treatment, etc. Furthermore, people who view work as processes understand that the ability to do their jobs depends on the quality of products (i.e., dialyzers) or services (i.e., training) they receive. A nurse depends on the pharmacist for medications, the pharmacist depends on the physician who writes the order, the physician depends on the policies, protocols, personnel, and equipment provided by the administration for the delivery of treatment and care. If a series of related tasks can be called a process, a group of related processes then can be seen as a *system*.

If a project team feels overwhelmed by its assignment at first, perhaps it is being asked to study a system instead of a process. Unless the team narrows the project's focus, it stands a chance of becoming mired and never making any progress. A project team should study only one process at a time. The only exception is when two or three processes are so closely related that it would be difficult to study them separately.

The team should first describe the process the facility uses to manage anemia. Describing a process involves listing all steps performed to display *how it is done now*. It is recommended that a process flow diagram (**Flow Chart)** be used to graphically display steps in the process. A flow chart outlines the sequence and relationship of steps in a process. Viewing a process in this graphic fashion assists the team in reaching a common understanding and knowledge of how decisions are made and work is accomplished.

Two types of process diagrams (top-down flow chart and detailed flow chart) are mentioned in this Guide. The top-down flow chart lists major steps in the total care process (*Fig. #12)*. This tool is useful in capturing an overall view of the interlinking relationships, subprocesses and multidisciplines contributing to the process and, ultimately, to the outcome. The team may then proceed to development of a detailed flow chart (*Fig. #10*) to describe one or more of the specific activities or steps in the process.

Fig. 12 **TOP-DOWN FLOW CHART**



To ensure an accurate description of the process, it is essential to invite participation from staff members who actually work in the process. If it is impractical to add additional staff members to the team at this point, an alternative approach to obtaining this crucial input must be sought. One suggestion is to post a draft flow chart in an area frequented by staff. Request their comments and supply Post-it™ notes for convenience.

◆ Compare Facility Process to External References

Comparing current practice (how it is done now) to practice expectations (how it is done by others) requires an external reference. The Anemia Clinical Algorithm provided in this Guide (*Fig. #10*) may be used as an external reference against which a dialysis facility may compare its approach to clinical management of anemia. The Anemia Clinical Algorithm is an example of a detailed flow chart graphically illustrating a *thought process*.

Algorithms are graphic outlines, diagrams or flow charts that describe each step in the *thought process* of clinical diagnosis and treatment. These tools show recommended alternatives and actions at each point in decision making, and can be used in analyzing processes of care and planning improvements.

Algorithms can serve a vital function in defining current practice and facilitating the continuous quality improvement process. Although algorithms have received much recent publicity as important elements in cost-cutting strategies, these instruments were initially developed and viewed as tools for use in quality activities more than 15 years ago. Several examples of the utility of algorithms and protocols now exist in the literature and describe their application in reducing variance and improving outcomes, for patient teaching, influencing physician behavior, and as a more effective approach than didactic education in medical training.

◆ Identify Potential Sources of Variation

Sources of variation refer to problems or deviations within the process (*not* with individual patients) that may contribute to low hematocrits. Some causes of variation may become apparent when the facility's process is flow charted (differences between *what is* and *what should be*). Additional causes of variation may be identified when the facility's approach/process is compared to the Anemia Clinical Algorithm. For example, the facility process may not include regular monitoring of iron stores, or may employ an EPO dosing protocol that is lower than generally accepted. Another possible source of variation may be the time lag between steps in the facility's process such as a three-week delay between the time lab results are posted and action is taken.

Many tools and techniques are available to assist teams in identifying potential sources of variation and several are discussed in the following narrative. Please note that there is no exact sequence to their use. These tools will assist the team in accomplishing crucially important tasks: 1) gathering ideas regarding variation from all team members based on their knowledge and expertise, and 2) identifying all possible sources of variation.

The team should conduct a **Brainstorming** session to generate a list of potential sources of variation (reasons for low hematocrits). Brainstorming is a powerful team technique useful in generating many ideas. Brainstorming assists in solidifying the team's working relationship while at the same time revealing useful information. This technique, explained further in the Tools section, may be used at several junctures in a quality improvement project and can be used in combination with other tools such as the fishbone diagrams or flow charts for performing process analysis.

After brainstorming is completed, teams may choose to pare down a list of possible sources of problems to a more manageable and *doable* list. This can be accomplished by categorizing the sources/causes according to level of control or influence. For example, Level 1 causes are those over which the group has direct control (they can definitely change). Level 2 causes are those over which the group can exert influence toward change. Level 3 causes are those over which the team has no control or influence and can result in tremendous wastes of energy if attempts are made at developing solutions. For this reason, Level 3 causes are crossed off.

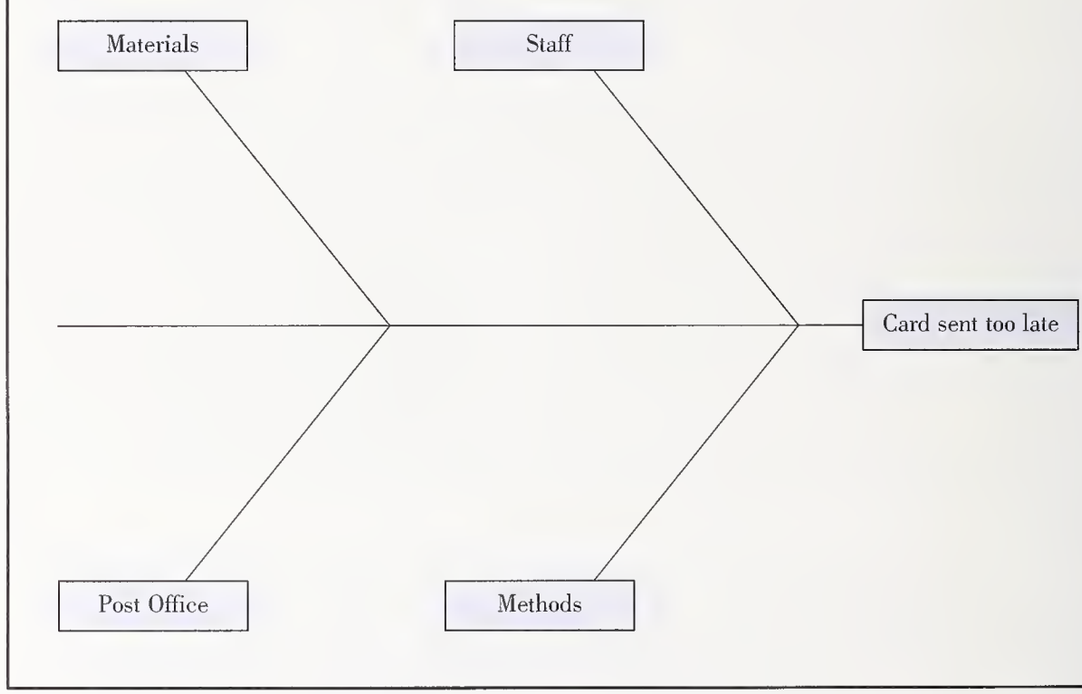
Another useful tool, the fishbone diagram (also known as a cause-and-effect or Ishikawa diagram) may be used to synthesize/refine, organize and display the ideas generated during the brainstorming session. The fishbone diagram has many applications (planning as well as problem solving) but is most useful in providing a detailed view of multiple factors contributing to performance outcome. Specifically, the fishbone diagram provides a visual representation of how the many common causes of variation (reasons for low hematocrits) act together to drive the problem (a low facility median hematocrit).

As an example, a procedure is outlined in Figures 13a-c and 14 that combines the use of brainstorming and the fishbone diagram to identify possible sources of problems. Another example (shown in Fig. #15a-d) illustrates the use of flow charting in process analysis. These procedures can be both an efficient and effective approach to engaging staff in CQI techniques.

Fig. 13a-c **STEPS USED TO CONSTRUCT A CAUSE-AND-EFFECT DIAGRAM**

- Place problem in box to the right.
- Select cause categories.

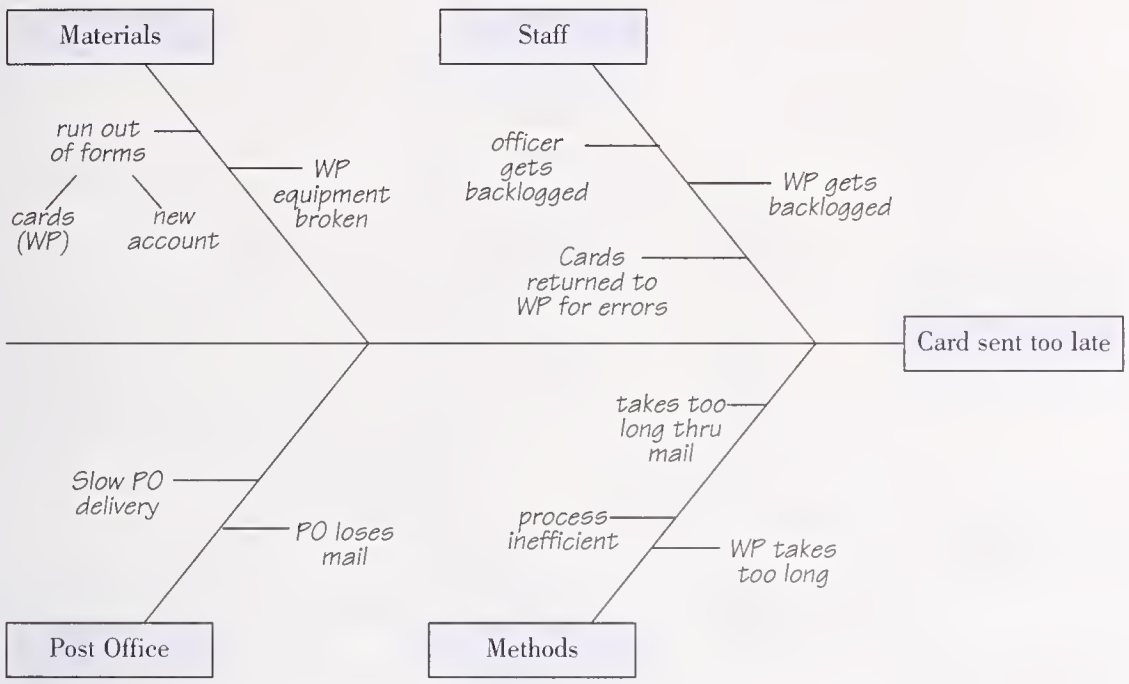
Fig. 13a



After the problem has been identified, the group using this diagram needs to determine which cause categories they wish to use. Although any number of categories can be used, at least three and not more than six are recommended. The classic cause categories are staff, equipment, materials and methods. Also useful are budget, regulations, etc.

- Brainstorm for causes.

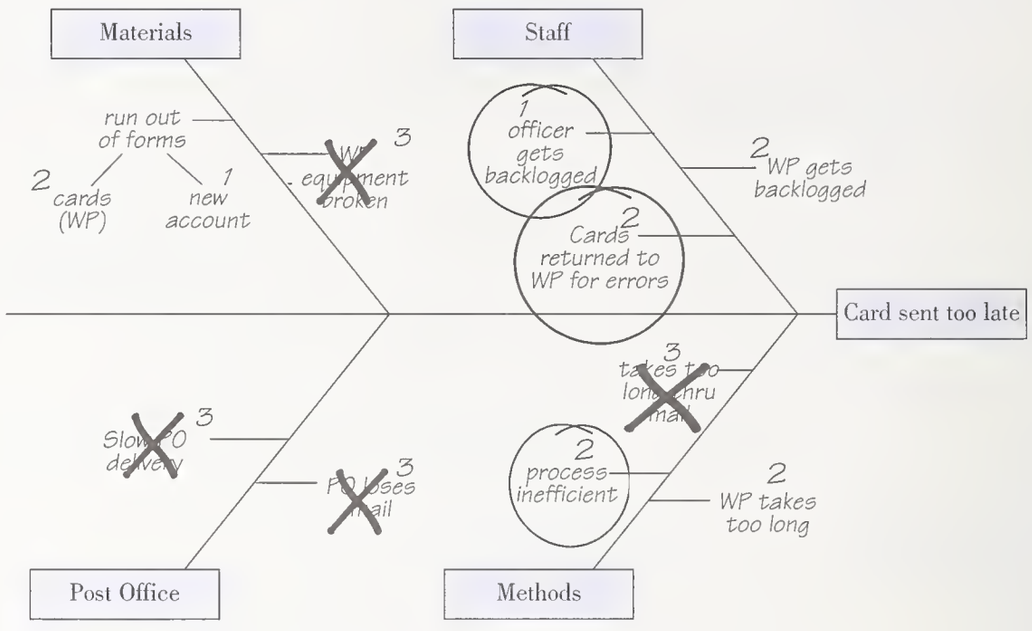
Fig. 13b



The next step is to brainstorm for causes of the problem. This can be done either systematically (one cause category at a time) or randomly (all cause categories at the same time). Causes can be broken down into greater detail by branching.

- Categorize the causes.
- Cross-off Level 3 causes.

Fig. 13c



Once all of the causes are listed, the group categorizes the causes according to level of control or influence. Level 1 (shown by "1") causes are those over which the group has direct control. Level 2 causes are those over which the group can exert influence. Level 3 causes are those over which the group has no control or influence. Level 3 causes can result in tremendous wastes of energy if attempts are made at developing solutions. For this reason, they are crossed off.

Fig.14 **CAUSE-AND-EFFECT DIAGRAM**

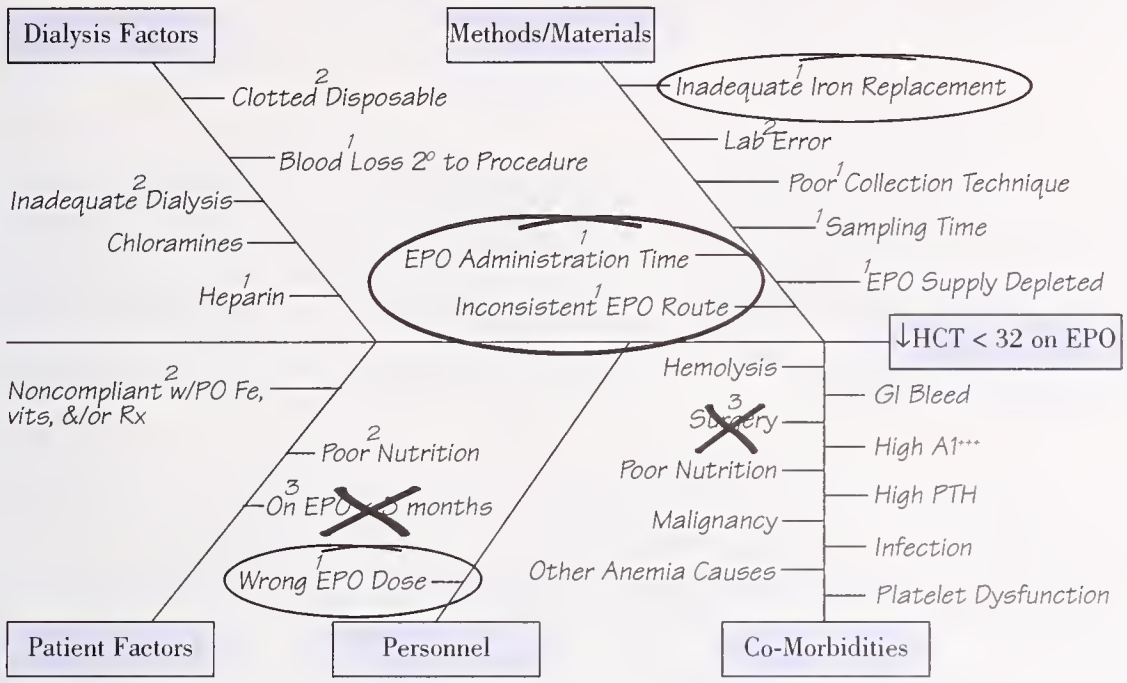


Fig.15a-d **PROCESS ANALYSIS WITH FLOW CHART**

Treatment of Anemia in Patients with Renal Failure

- List steps.

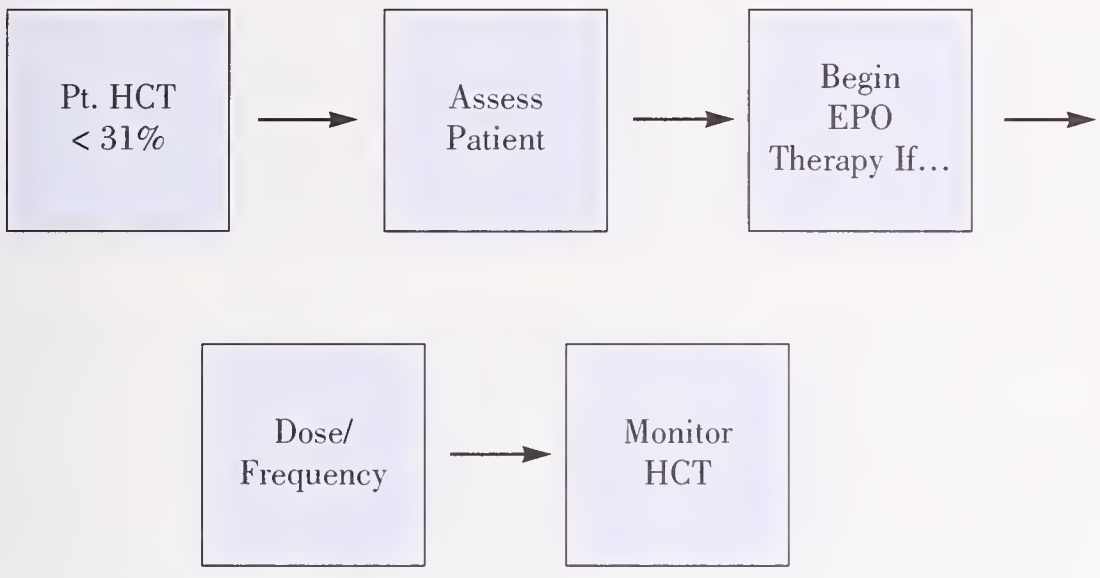
Process Steps
Treatment of Anemia

1. Pt HCT < 31%
2. Pt assessment
3. Prerequisites for EPO therapy
4. Dosing and frequency
5. Monitor HCT

After the project has been identified, the group lists the steps involved in the process being analyzed. The steps should be kept on a very general basis. Decisions or alternative steps are not identified.

- Place steps in boxes.
- Connect boxes with arrows.

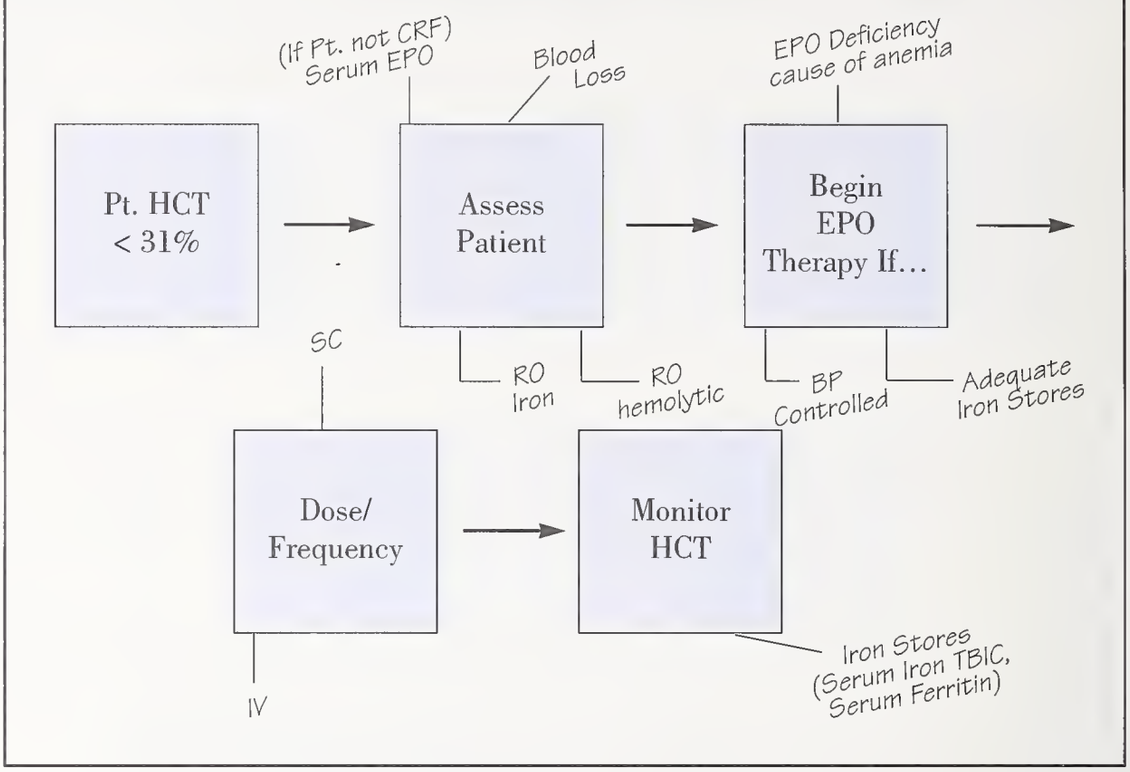
Fig. 15a **PROCESS ANALYSIS DIAGRAM**



Once all of the steps are listed, they are placed in boxes going from left to right, and top to bottom. Enough space to accommodate some brainstorming must be left between the lines of boxes. The boxes are then connected by arrows. These arrows reflect the direction of the process's flow.

- Brainstorm for causes for each step.

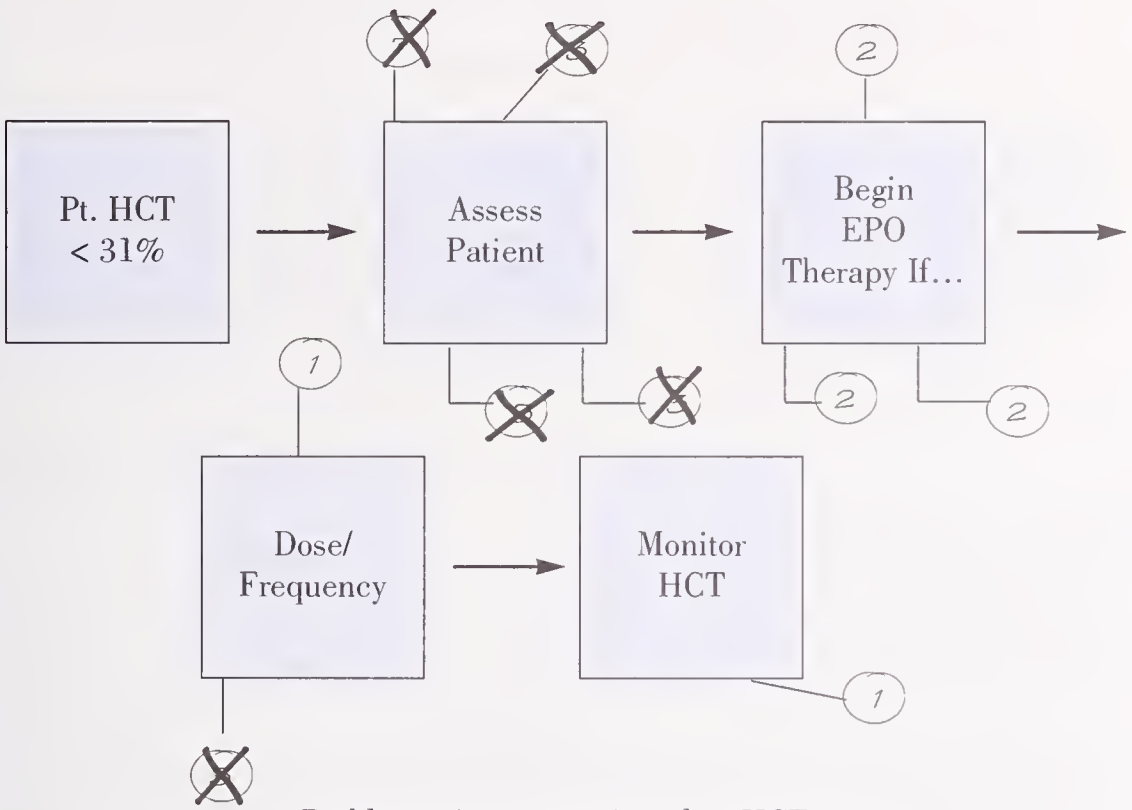
Fig. 15b **PROCESS ANALYSIS DIAGRAM**



The next step is to brainstorm for causes of the problem. This can be done either systematically or randomly. Causes can be broken down into greater detail by branching.

- Categorize causes.
- Cross-off Level 3 causes.

Fig. 15c **PROCESS ANALYSIS DIAGRAM**

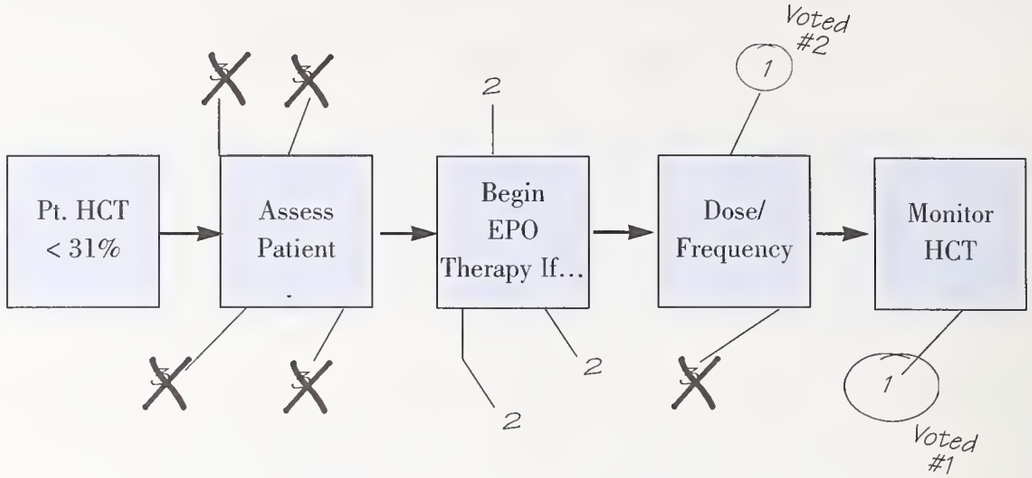


Problem: Anemic patient, low HCT

Once all of the causes are listed, the group categorizes the causes according to level of control or influence. Level 1 (shown by "1") causes are those over which the group has direct control. Level 2 causes are those over which the group can exert influence. Level 3 causes can result in tremendous wastes of energy if attempts are made at developing solutions. For this reason, they are crossed off.

- Vote on major causes to problem.

Fig. 15d **PROCESS ANALYSIS DIAGRAM**



RESULTS FROM VOTING.

1. *Monitor HCT*
2. *Dose/Frequency*

To complete the diagram, the group then votes on the causes that they think are contributing the most to the problem. The vote can be done either by a show of hands or by hidden ballot.

◆ Confirm Which Sources of Variation Are Real.

Confirming potential sources of variation (testing hypotheses regarding source of the problem) requires additional measurement. The team may have developed an extensive list of potential sources, but may *choose* to measure or test only a few hypotheses due to time and resource restraints. Teams are cautioned, however, to avoid reducing the possibilities to a single idea or hypothesis at this stage.

Multivoting is a team technique useful in reducing a large number of ideas to a manageable few. Multivoting can be used at any step in the improvement process to reach consensus on reducing a set of alternatives. Directions for multivoting are located in the Techniques section. Please note that multivoting will not be needed at this step if the team elects to collect data on all the potential sources of variation identified.

A simple form of measurement can be accomplished by using a **Checksheet** to count how often the *potential sources of variation* identified by the team actually happen. In contrast to the checksheet used to gather baseline hematocrit data in Step Two (*Fig. #5*), this checksheet is designed as a matrix on which the data collector(s) records a check mark each time the *source of variation* occurs. This necessitates that the team develop an operational definition to determine specifically what constitutes an occurrence of each source of variation. For example, if the team identified low iron stores as a potential source of variation, the team must determine what constitutes low iron stores. The agreed upon operational definition for low iron stores might be: check *yes* if saturation < 20% or ferritin < 100. The data collector(s) would make a check on the checksheet each time a patient in the selected sample had either a saturation < 20% or a ferritin < 100. Team agreement upon precise operational definitions decreases the likelihood of subjective interpretations in data collection thus enhancing the reliability of the data collected. Further, it is useful to keep in mind that if an item cannot be defined, it cannot be measured. An example of a checksheet and corresponding operational definitions appears in Fig. 16a-b.

* Template available in Appendix.

Fig. 16a **CHECKSHEET, MATRIX – BLANK FORM***

Checksheet for Causes of Anemia

Patient Sample: All patients with hct < 32% on two or more occasions _____, 199__
(date)

FACTORS ↓ PATIENT ID→						AGGREGATE
Modality						HD | PD | ALL
Hematocrit						
Dialysis Factors						
Inadequate Dialysis						
Clotted Disposable						
Blood Loss 2° Procedure						
Methods/Materials						
Inadequate Iron Replacement/Stores						
Imferon given						
Oral Fe preparation prescribed						
EPO Dose Held or Reduced						
Lab Error						
EPO Administration Time						before | end | after
EPO Supply Depleted						
EPO Route						SQ | IV
Personnel						
Wrong EPO Dose						
Patient Factors						
Volume Expansion						
On EPO < 3 Months						
Co-Morbidities						
Hemolysis						
GI Bleed						
Surgery						
Poor Nutrition						
Malignancy						
↑ Al +++						
↑ PTH						
Infection						
Platelet Dysfunction						
Other Anemia Causes (Hemoglobinopathy, B_{12}, Folate or Pyridoxine deficient)						

Fig. 16b **CHECKSHEET, MATRIX – WITH OPERATIONAL DEFINITIONS**

Operational Definitions for Anemia Chechsheet

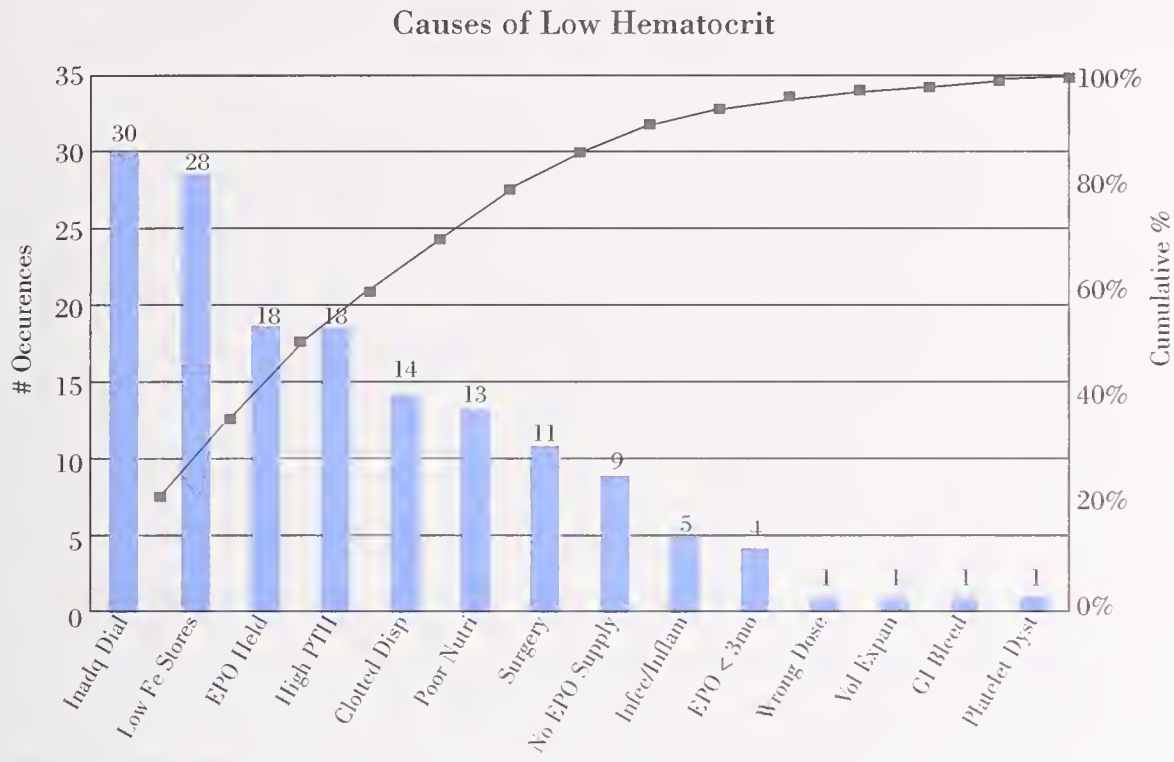
FACTORS ↓	OPERATIONAL DEFINITIONS
Modality	Hemodialysis or peritoneal
Hematocrit	Use lowest HCT during study time
Dialysis Factors	
Inadequate Dialysis	KT/V < 1.2 *or* 2 consecutive treatments missed or < prescribed (time, BFR or dialyzer) before HCT<32
Clotted Disposable	Dialyzer or lines
Blood Loss 2° Procedure	Line rupture *or* excessive blood loss post Rx defined/documented by care taker
Methods/Materials	
Inadequate Iron Replacement/Stores	Saturation <20% or ferritin <100 or serum Fe <50
Imferon given	Parenteral iron administered during past 8 weeks
Oral Fe preparation prescribed	Oral iron med *ordered*
EPO Dose Held or Reduced	EPO dose held or reduced @ least 10 days before HCT noted as <32
Lab Error	Single low HCT value which was repeated & within patient's usual range (acceptable hct) without intervention
EPO Administration Time	**Before** = given >15 min before Rx end; **end** = given 0-15 min before rx end; **after** = given 0 to 15 min *after* Rx end
EPO Supply Depleted	If unit is out of EPO, flow sheet will reflect this as reason EPO not given
EPO Route	Enter SQ or IV
Personnel	
Wrong EPO Dose	Any dose differing from prescribed amount
Patient Factors	
Volume Expansion	Predialysis weight > 12 lbs over target
On EPO < 3 Months	Self explanatory
Co-Morbidities	
Hemolysis	May be documented as R/O hemolysis; haptoglobin may be ordered
GI Bleed	Positive guaiac *or* positive emesis *or* evidence of bleeding during past 3 months
Surgery	During past 3 months
Poor Nutrition	Albumin < 3.5 *or* weight loss > 15% ideal body weight (past 3 mo) *or* malabsorption
Malignancy	All forms (excluding skin) currently active; check recent H&P or problem list
↑ Al^{+++}	> 100 during past 3 months
↑ PTH	> lab's upper normal limit during past 3 months
Infection	Acute or chronic infectious or inflammatory process of > 10 days duration (osteomyelitis, pneumonia, access infection, etc.)
Platelet Dysfunction	May find lab report (nonroutine) for bleeding time
Other Anemia Causes (Hemoglobinopathy, B_{12}, Pyridoxine deficient)	Check problem list for hemoglobinopathies. For B_{12}, Folate or Pyridoxine deficiencies, check lab reports (nonroutine) with values < normal.

After developing the checksheet and operational definitions, the team must select a patient sample and time frame for data collection. The patient sample might be the facility's entire population, a randomized representative sample, or a subset such as all patients with hematocrits below the facility's treatment goal. The patient sample and time frame might be all patients with HCT < 32% on one or more occasions during the previous two months. (The specific hematocrit level chosen in this example was driven by the facility's treatment goal.) The time frame is somewhat flexible and is driven by facility size, record availability and other factors. A balance must be achieved between obtaining sufficient information to present a valid, representative picture without overburdening team members/data collectors. A very small facility may need to collect data over a four-month period while a larger facility may gather a representative picture within one month.

The team should also decide *who* will collect the data, ensure that they have the operational definitions, and set an expected date of completion (*when*). Once the data have been collected on the checksheet, it must be aggregated and displayed for team analysis.

Findings from this data collection effort can be displayed in a **Pareto Diagram** (*Fig. #17*). The Pareto principle states that 80% of the problem is usually caused by 20% of the sources. Pareto analysis will assist the team in focusing on those sources of variation which are most likely to have the greatest impact on outcome. The Pareto diagram displays the data in bars in decreasing order of frequency from left to right, thus visually displaying the *vital few* sources, which are likely to be areas of highest payback, from the many other important but less frequent sources.

Fig. 17 **PARETO ANALYSIS**

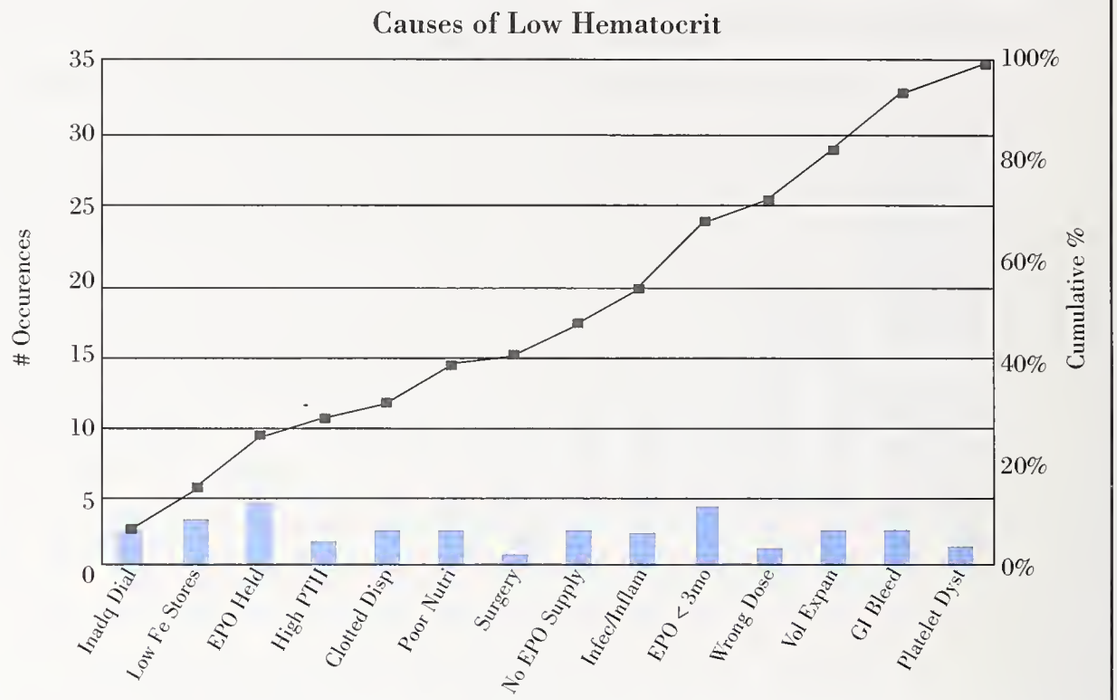


Based on data from 45 HD patients w/ HCT < 32 on 2 or more occasions between 10/23/94 & 11/28/94

If the team's Pareto diagram does not separate a few *vital* sources which cumulatively account for approximately 80% of the problem (low hematocrits). the team must reconsider the potential sources of variation because previous activities (brainstorming, etc.) have not captured the major sources of variation. If the team's Pareto diagram resembles Figure 18. (i.e.. is *flat*) consider the following common pitfalls:

- Wrong people on the team – re-examine team composition. Do enough team members *work in the process?*
- Process inaccurately or incompletely illustrated on flow diagram. Ask other staff to review flow chart.
- All possible sources of variation were not identified. Review brainstorming list, fishbone or process analysis diagram to ensure that all possible sources of variation were identified and were not deleted during list reduction activities (multivoting).
- The wrong measures were used to define the source of variation for data collection. Review the checksheet and the operational definitions for accuracy and clarity.

Fig. 18 **FLAT PARETO**



Based on data from 45 HD patients w/ HCT < 32 on 2 or more occasions between 10/23/94 & 11/28/94

All of the information on the checksheet and corresponding Pareto analysis presented in this section were not appropriate for inclusion on the Pareto diagram. The team should consider additional methods of data display such as tables, histograms, and scattergrams to interpret these findings. An explanation of histograms and scattergrams is included in the Tools section.

Select One Key Source of Variation

At the end of Step Three, the team should have identified and confirmed, through data collection and analysis, **a major source of variation** in the dialysis facility's process for managing anemia. It is important that the team work through the activities of this step slowly and carefully. Choose one source of variation over which the team has control.

In Step Four, the team will delve deeper into this one confirmed *source* to search (and confirm) a *root cause*. Step Five activities will be to design corrective actions focusing on the source (Step Three) and root cause of variation (Step Four). If the team has not considered all points of view nor measured to confirm a source, it risks ineffective use of time, effort and resources in the remaining steps of the RoadMap.

HOW TO'S

- Read about and discuss variation theory. One suggestion is to read Dr. Donald Berwick's journal article entitled "Controlling Variation in Health Care: A Consultation from Walter Shewart," *Medical Care*, December, 1991, Vol. 29, No. 12. A copy can be obtained from your Network office.
- Review the principles of flow charting and develop a detailed flow chart of anemia management as it is currently performed in your facility.
- Compare your process for anemia management to an external reference such as the Anemia Clinical Algorithm (*Fig. #10*).
- Brainstorm for *all* possible sources of variation. If it is necessary to shorten the list of possibilities, team consensus must be reached. Multivoting is one technique that can be used. (Refer to Techniques section.)
- Develop a checksheet and operational definitions.
- Plan data collection (sample, time frame, who will collect, estimate completion time).
- Collect and aggregate data.
- Display and analyze data (Pareto analysis).
- Select one source of variation for further investigation (Step Four) and action (Step Five).
- Continue to update run chart.
- Continue to record team progress.

* Template for this page available in Appendix.

CHECKLIST FOR STEP THREE*

At the end of Step Three the team should have accomplished the following activities and reached consensus on answers to the following questions:

☑ Discussed the concept of variation.

Was the team able to identify examples of both common cause and special cause variation?

☑ Developed a flow chart of the process.

Has the process for managing anemia been fully and accurately described?

☑ Compared the facility's process to others.

Have appropriate external references been used to compare practice?

☑ Identified sources of variation.

Have all potential sources of variation been identified?

☑ Collected and analyzed data.

Were major sources of variation confirmed?

☑ Selected ONE source of variation for further investigation and action.

Does the team agree that this is a valid problem over which the team can exert some control or influence?

☑ Collected additional monitoring data.

Has the team continued to monitor the process by updating the run chart?

☑ Reported team progress.

Has progress report, storyboard or storybook been updated appropriately?

TEAMS, TOOLS AND TECHNIC

STEP FOUR

STEP FIVE

STEP SIX

STEP SEVEN

OBJECTIVE

Search for root causes of variation and select an area for improvement

ACTIVITIES

- Review activities conducted in Step Three (concept of variation, process analysis).
- Perform process analysis (as detailed in Step Three) on confirmed source of variation.
- Confirm root causes of variation (plan, collect and display data).
- Select an opportunity for improvement. (Link root cause to outcome measure and the opportunity statement from Step Two.)
- Continue to monitor process and update run chart.
- Continue progress report (storyboard/storybook).

DISCUSSION POINTS

Review Activities Conducted in Step Three (Concept of Variation, Process Analysis)

The activities of Step Four mirror those of Step Three. Before you proceed with Step Four, review the team's activities from Step Three.

In Step Three, your team described how anemia is currently managed in your dialysis facility. You compared your overall approach to treatment with an external reference, and identified and confirmed sources of variation. Now it is time to search for root causes of the confirmed source of variation. It is necessary to determine and understand the *root cause* of a source of variation before an appropriate improvement can be planned.

Perform Process Analysis (as Detailed in Step Three) on Confirmed Source of Variation

Now you are going to perform process analysis of a confirmed source of variation in search of its root causes. Root causes can usually be found by delving deeper into subprocesses and interlinking processes such as managing iron stores, adequacy of dialysis, administration of medications, or patient teaching or counseling. The search for root causes uses the same tools and techniques detailed in Step Three. However, in this step a subprocess responsible for a confirmed source of variation will be analyzed.

As you begin to examine the subprocesses, other clinicians (coworkers) should be asked for their input in flow charting the subprocesses, interpreting the data and searching for causes and contributing factors. The team will probably need to: flow chart the subprocess, brainstorm for all possible causes related to the variation, develop a checksheet, and collect data to confirm that the causes are real. Data displays may include histograms, scattergrams, and/or Pareto charts. This time when the data are displayed, the team will be viewing *root causes* of the problem.

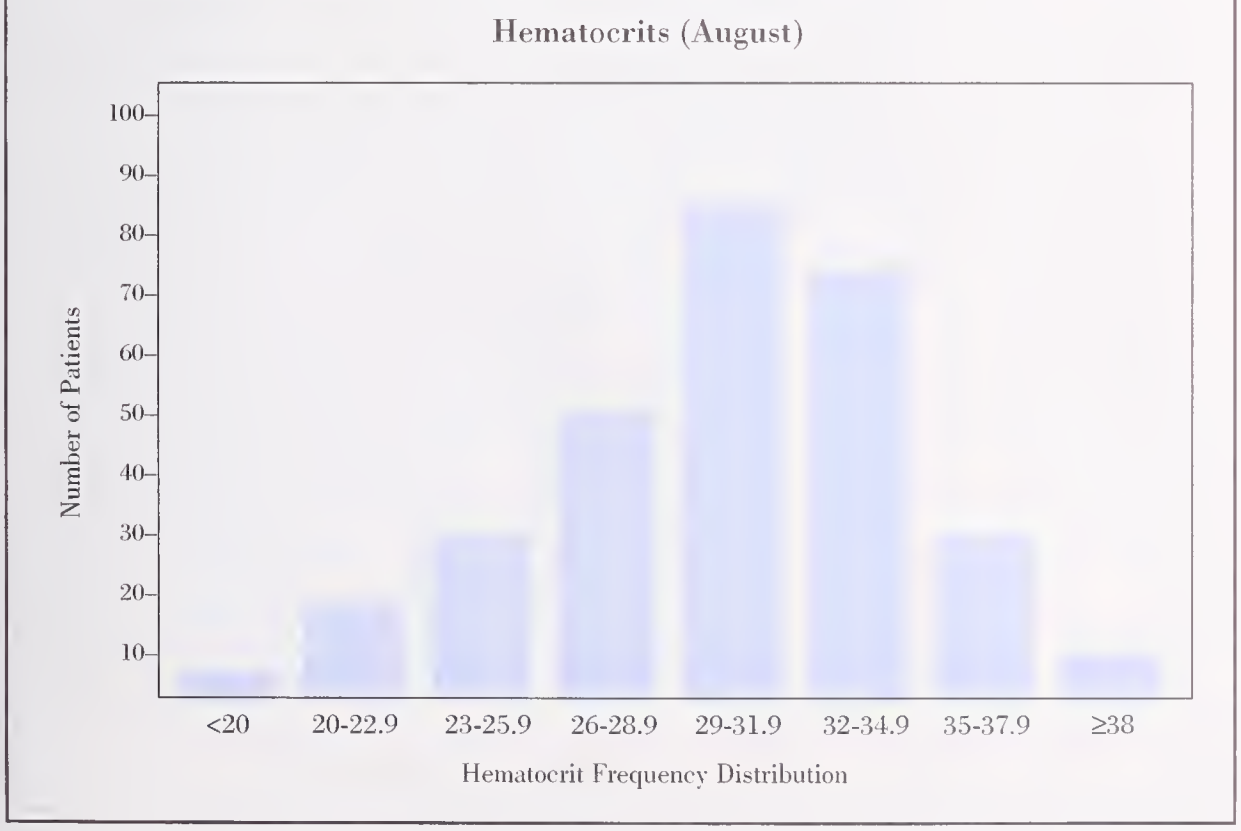
◆ Confirm Root Causes of Variation (Plan, Collect and Display Data)

At the end of Step Three, your team should have identified and confirmed a major source of variation in the facility's process for managing anemia. There are many techniques that can be used to help you analyze and display variation. Variability can be displayed in graphic form using a **Histogram** (Fig. #19). A histogram is a variation of the Pareto chart which takes measurement data, rather than events, and displays their distribution. The histogram reveals the amount of variation that any process has within it. The variable in question, such as hematocrit or serum albumin, is displayed on the x-axis, and grouped into ranges. On the y-axis is the number of patients falling into each of those ranges. A typical distribution shows the greatest number of facilities at the center measurement with roughly an equal number of facilities falling on either side of the point. Many repeated samples of data under statistical control follow this pattern. Other data displays might show patterns with the data *piled up* at points away from the center. Such a distribution is referred to as being *skewed*. The important thing to remember is that you are looking for surprises such as distributions that should be naturally *normal* but are not, or *normal* distributions which should be skewed to the right or left.

X-AXIS
The horizontal axis in a chart; the items being measured.

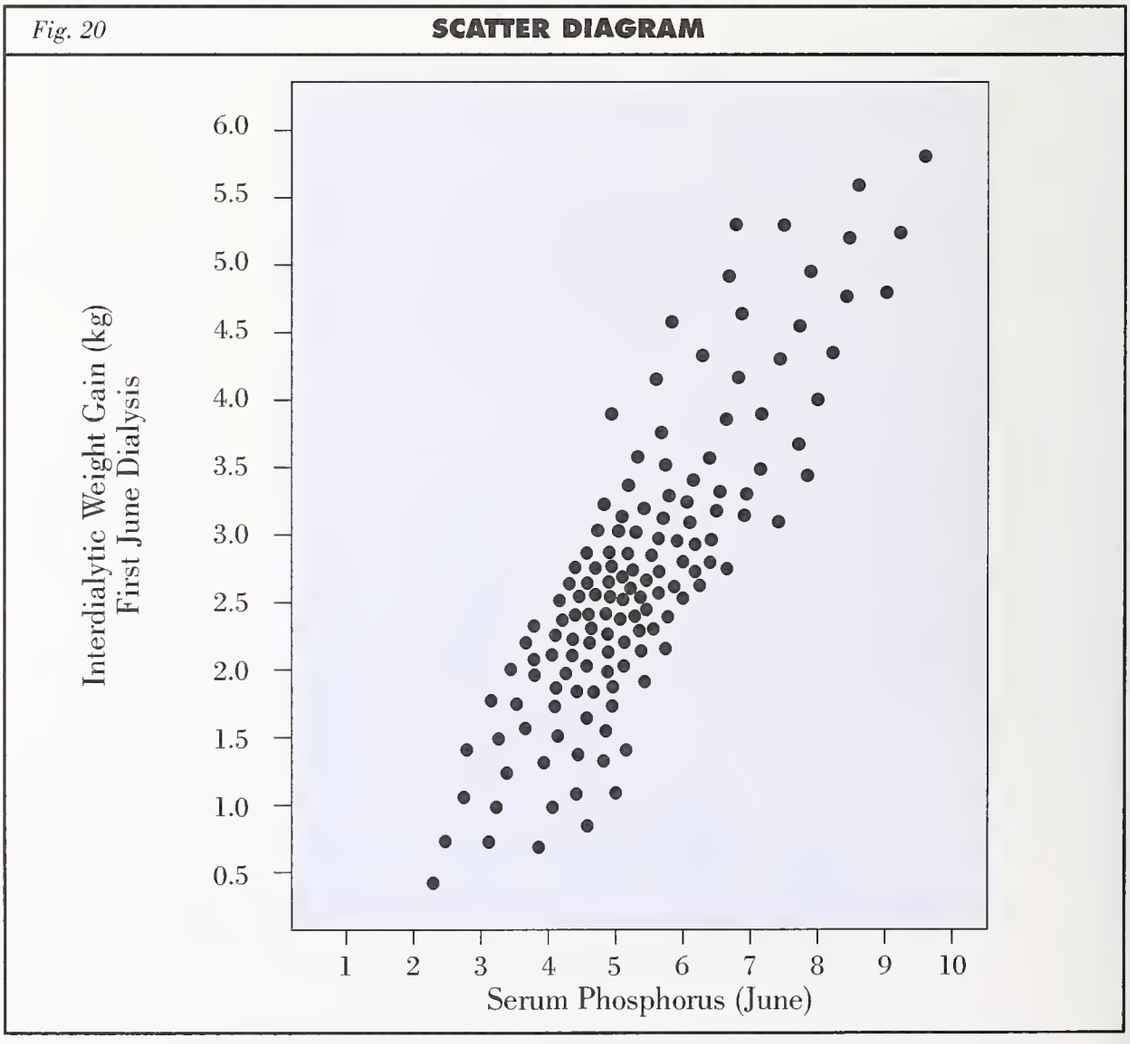
Y-AXIS
The vertical axis in a chart; contains the numerical range of the items being measured.

Fig. 19 **HISTOGRAM**



A **Scatter Diagram** (*Fig. #20*) is used to study the possible relationship of one variable to another. It is used to test for possible cause-and-effect relationships. It cannot prove that one variable causes the other, but it does make clear whether a relationship exists and the strength of that relationship. Variable 1 is plotted in quantitative terms on the x-axis, variable 2 in quantitative terms on the y-axis. In order for a scatter diagram to be useful, generally it is necessary to have at least 50-100 paired samples of data. Once the data points are plotted, the pattern of point distribution is examined, and it can be ascertained visually whether there may be a positive correlation. The direction and *tightness* of the cluster give you a clue as to the strength of the relationship between variable 1 and variable 2. The more this cluster resembles a straight line, the stronger the correlation between the variables. This makes sense; a straight line would mean that every time one variable would change, the other would change by the same amount. Patterns and meanings that scatter diagrams can have are explained further in the Tools section.

Fig. 20 **SCATTER DIAGRAM**



Scatter diagrams are often used in combination with a fishbone or Pareto chart. They are more advanced tools for analyzing the extent to which documented causes of problems might be related to one another. Many teams will not advance to the use of these diagrams during their first try at process improvement, especially if process problems are readily recognized. However, it is a valuable tool for use in future projects.

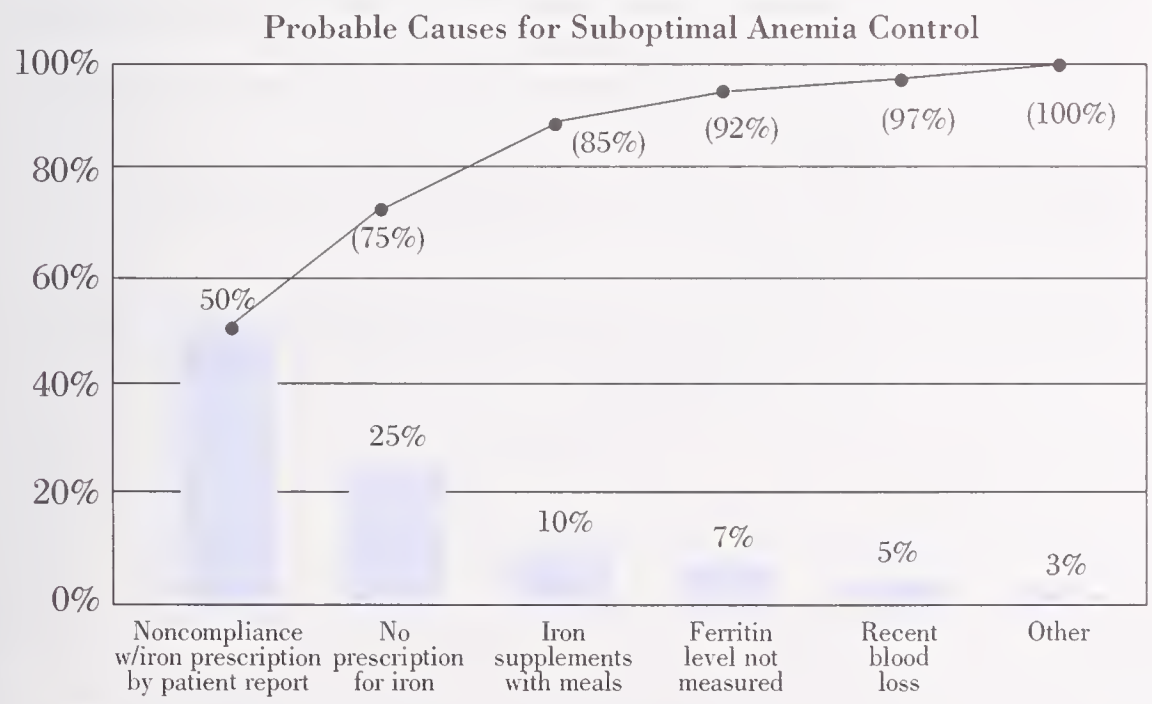
Each cycle of process analysis, data collection and presentation may require a series of meetings to continuously clarify knowledge, and to share results with other clinicians for further interpretation of the data.

◆ Select an Opportunity for Improvement

What key *cause* will have the most desired effect on the outcome (link the root cause to an outcome measure)? The team is at a point in the overall quality improvement process at which it will need to decide when to stop process investigation and begin planning improvement actions.

The team should use the opportunity statement developed in Step Two, together with the Pareto diagram that displays *root cause* data (Fig. #21), to begin the decision making process. In making a decision, consideration should be given to determining how much control or influence (leverage) the team actually has to create change.

Fig. 21 **PARETO DIAGRAM - ROOT CAUSE**



The Pareto chart allows the team to categorize occurrences and focus on those that are most frequent and most important. But teams faced with a confirmed source of a problem and related causes may still be uncertain what to work on, or what to work on first. Two group techniques useful for establishing *consensus* may be helpful: **Force-Field Analysis** and **Selection Matrices**.

Force-field analysis is used to identify the sources and factors in place that support or work against the solution of an issue or problem so that the positives can be reinforced and/or the negatives eliminated or reduced. By performing force-field analysis, both the positives and negatives of a situation are easily compared, people are forced to think together about all the aspects of making the desired change a permanent one, people are encouraged to agree about the relative priority of factors on each side of the *balance sheet*, and people are encouraged to reflect honestly on the real underlying roots of a problem and its solution. The final goal of force-field analysis is to eliminate or reduce the effect of restraining factors and increase or strengthen the positive counterforces.

Selection matrices are used to narrow down options through a systematic approach of comparing choices by selecting, weighting, and applying criteria.

A selection matrix might include some of these commonly used selection factors:

Control .....The extent to which the group controls the problem and can control the solution.

Importance .....The seriousness or urgency of the problem.

Difficulty .....A judgment about the relative difficulty of working through the problem to a solution.

Time .....A judgment about the relative length of time it will take to resolve the problem.

Return on Investment .....The approximate, expected payoff from solving the problem.

Resources.....The extent to which the resources required to solve the problem are accessible to the group (e.g., people, time, money, equipment).

Be sure everyone understands any other criteria used on the worksheet.

Figure 22 shows an example of force field analysis. Figure 23 shows an example of how a facility in the pilot phase of the Anemia Project used a selection matrix in choosing an area for improvement.

Fig. 22a **FORCE FIELD ANALYSIS**

As Is
Low Staff Morale in Dialysis Unit (rating 1.7) → *Desired State*
Increase morale (rating 4.0)

Helping			Hindering
Staff interviews	→	←	Inconsistent recognition
Small discussion groups well received	→	←	Inadequate numbers of staff
Quarterly recognition program	→	←	No management training
Problem-solving teams established	→	←	Outdated policies and procedures
		←	Managers not involved in problem solving

* Template available in Appendix.

Fig. 23 **SELECTION MATRIX***

Example from Pilot Phase of Anemia Project

Possible Solutions	Cost Effective - 1 2 3 4 +	Value to Customer - 1 2 3 4 +	Can We Implement? Yes/No	Support Objectives? Yes/No	Can We Meet Deadline? (12/94)	Positive Effects EPO - 1 2 3 4 +	Adverse Effects - 1 2 3 4 + (worse)	No Compliance (Patient) Yes / No
Adjust all patients' oral iron supplements to at least 650 mg/day	Patient 1 Unit 4	4	Y	Y	N	4	3	N
Administer I.V. iron dextran to all patients with serum Ferritin <100 mcg	Patient 2 Unit 3	3	Y	Y	Y	3	3	Y
Facility to provide minimal lab screen for assessing iron stores	Patient 4 Unit 1	2	?	Y	?	1	1	Y
Renegotiate HMO contract to provide better coverage of ancillary services	Patient 3 Unit 3	3	?	?	?	1	1	N/A
Develop patient educational program re iron stores and relationship of iron to EPO use and efficacy	Patient 4 Unit 3	3	Y	Y	N	1	1	N

Step Four concludes when the team has reached consensus on an opportunity for improvement. The team will begin planning the improvements in Step Five.

◆ Continue to Update the Run Chart and Record the Team Progress as Discussed in Previous Steps

HOW TO'S

- Begin with a confirmed source of variation (i.e., iron stores are low).
- Flow chart subprocess.
- Brainstorm potential factors or variables associated with this problem area (i.e., poor dietary intake of iron, iron supplements not available, patient non-compliance to medication, infection, etc.), using a cause-and-effect diagram.
- Develop a checksheet and operational definitions.
- Plan data collection cycle (sample, time frame and collectors).
- Collect and aggregate data.
- Display and analyze the data.
- Select root causes of variation for improvement action.
- Continue to add data to run chart.
- Continue to record team progress.

* Template for this page available in Appendix.

CHECKLIST FOR STEP FOUR*

At the end of Step Four the team should have accomplished the following activities and reached consensus on the answers to the following questions:

- ☑ Identified a major source of process variation.
  Did we begin with a confirmed source of problems (variation)?
- ☑ Developed a flow chart for the subprocess associated with the confirmed source of variation.
- ☑ Brainstormed for possible root causes of variation.
  Have we adequately described and analyzed all potential causes of the confirmed source of variation?
- ☑ Executed a data collection cycle.
  Have we confirmed that these root causes are real?
- ☑ Displayed and analyzed data.
  Have we ranked the confirmed root causes (Pareto analysis)?
- ☑ Selected a root cause for improvement planning.
  Did we revisit the Opportunity Statement for the desired state?
- ☑ Sought feedback from members outside of the team.
  Do we all agree on the specific area(s) (root causes) chosen for improvement?
- ☑ Continued monitoring process.
  Are we continuing to monitor the process and update the run chart?
- ☑ Continued progress reporting.
  Have we updated our progress report (storyboard/storybook?)

OBJECTIVE

Design and Implement An Improvement Trial

ACTIVITIES

- Generate as many ways as possible to improve.
- Clarify and analyze each potential solution and reach consensus on which improvement to try first.
- Design a plan for implementing the trial improvement.
- Initiate the trial improvement.
- Continue to monitor and update run chart.
- Continue progress report (storyboard/book).

DISCUSSION POINTS

The ROADMAP or quality improvement process the team has been following thus far has been one of diagnosis (identifying cause of variation). It is now time to plan treatment (ways to improve the care process). As in the medical model, a well thought-out treatment plan is the first step, followed by delivery of care, monitoring, evaluation, and continuing treatment if the approach works or planning a new approach if it doesn't.

Steps One to Four of the Guide have directed the team to explore and analyze many potential sources and related causes of problems (variation) and to FOCUS on one specific cause for improvement. Step Five is the beginning of a Plan, Do, Check, Act Cycle (PDCA) during which an improvement to a process (or subprocess) will be designed, pilot tested, and monitored – *Plan* and *Do*. In Step Six, you will *Check* – evaluate the improvement pilot test. If determined successful, in step Seven you will *Act* to implement the improvement throughout the organization. (For example, implementing a process change that involves all patients, not just a selected few.)

Planning Improvement Requires

- Brainstorming ways to improve.
- Prioritizing and selecting one opportunity.
- Developing a plan of who does what, when, and with what tools and training?
- Deciding how the improvement will be monitored. (What baseline data should be collected to monitor change?)

◆ GENERATE AS MANY WAYS AS POSSIBLE TO IMPROVE

At the end of Step Four, the team should have confirmed root causes of variation and identified an opportunity for improvement. The team is now ready to *Plan* a trial improvement. The first thing the team should do is to generate as many ways as possible to improve the cause(s) of variation. The team must avoid rushing to a seemingly apparent solution and consider as many ways as possible to improve the problem (cause of variation). The team will probably use techniques such as brainstorming in generating solutions for improvement.

◆ Clarify and Analyze Each Potential Solution and Reach Consensus on Which Improvement to Try First

* Template available in Appendix.

Consider the following in selecting an improvement opportunity:

- What can we change that will lead to improvement?
- How will we know this change is an improvement?
- How do we *pilot* an improvement before organizationwide implementation?

The team will need to discuss each potential solution and reach consensus on which improvement is the *best solution* before continuing on to develop or *Plan* the improvement trial. Techniques that will be useful to the team in determining the *best solution*, as in Step Four, include a solution selection matrix and/or force–field analysis. The team should keep this question in mind as it determines which solution (improvement trial) to implement, "Do we have control over this potential improvement?"

◆ Design a Plan for Implementing and Evaluating the Trial Improvement

Once agreement has been reached on a possible solution to be pilot tested (*Fig. #24*), the team needs to develop a plan that addresses the following: *who does what? when?* and *with what tools and training?*

Fig. 24 **TEAM ACTION PLAN FORM***

Problem Description:	*Inadequate Iron Stores in 30% of Patients; Inconsistent Approach to Iron Management*
Improvement Goal:	*Improve Iron Status of All Patients*
Proposed Solution:	*Develop Standardized Iron Replacement Protocol*

What	Who	Target Date	COMMENTS
1. *Flowchart Iron Replacement Protocol*			
2. *Rewrite Orders/Procedures*			
3. *Train/Inform Staff*			
4. *Implement New Process*			
5. *Gather Data on Implementation*			
6. *Check/Act on Impact of New Process*			

The team must decide on how the improvement will be monitored, including what baseline data should be collected to monitor change and measure the improvement (change). The team also needs to decide on what criteria to use to determine if the trial improvement was successful. (Did it do what you wanted it to do?) The plan should include a time line that outlines how long it will take to complete the improvement trial, including the evaluation of the results of the trial.

Do – Initiate a Trial Improvement.

To Do means to implement the trial solution and to maintain records of what is being learned as the trial approach is undertaken. Similar to drug trials, an improvement trial is generally limited to a small sample group – i.e., one shift of patients, one physician's patients, or patients grouped by outcome such as HCTs < 25%. Confining the trial to a subset increases control of the trial procedure, limits data collection, and minimizes patient exposure to alterations which may not improve outcomes.

Listed below are some key steps to ensure that implementation of the trial improvement is as successful as possible.[18]

- *Divide the solution into sequential, easily manageable steps.*
  This will give a set of reference points which can be used to determine whether or not implementation is on target (time, costs, etc.) and meeting the stated objectives.

- *Ensure that everyone knows what he or she must do.*
  Set clear, measurable and unambiguous objectives or task statements for everyone who is going to be involved in implementation. Communicate these clearly and ensure, as far as possible, that nothing is left open to misinterpretation or guesswork.

  Everyone means all staff who will be involved in the improvement trial. If the trial involves changes in procedures, all staff must understand the objectives of the trial and the temporary changes. Additionally, the team should establish a feedback mechanism to ensure that questions are answered consistently and problems are identified quickly.

18. *NYS Process Training Guide.* Albany, NY: State of New York, Dept. of Health.

- *Develop a commitment strategy.*
  Define clearly whose commitment is needed and how to secure it, both in the initial stages (gaining commitment) and once implementation is in progress (maintaining commitment). Bear in mind the very large differences between the passive commitment on which so many people rely (changing a procedure on paper) and the active commitment necessary for success (changing behavior of staff actually performing the procedure).

- *Establish a criteria for monitoring.*
  Set up a simple but thorough monitoring system to track whether or not specific tasks are being performed or short-term targets are being achieved as planned.

- *Ensure that data will be collected.*
  Your implementation of the solution will generate change, and it is essential to have the measurements and data collection mechanisms set in place for overall evaluation. The data that will be required to accurately evaluate the trial must be identified and data collection tools and methods established prior to implementation. How will the changes be measured? How will the team know that the change is an improvement? As part of your implementation checklist, ensure that the data you will need to evaluate your solution are going to be available.

- *Define contingency plans.*
  Contingency planning need not be an extensive, involved activity. It is simply a step in the planning process during which the team attempts to anticipate *what can go wrong with our solution plan* before the trial is initiated, and what actions will be taken if problems occur. Often, contingency planning serves as a *dress rehearsal* for the improvement trial and helps the team uncover operational problems in advance.

Some points to consider when establishing contingency plans are:

- What specific problems (opportunities) may occur as a consequence of the proposed change?
- How probable are they?
- How much impact would they have if they occurred?
- What can be done to prevent these potential problems from occurring? (Should these opportunities to learn be allowed to occur?)
- How will the team know that the problem (opportunity) has occurred?
- How will the team deal with unanticipated problems (opportunities)?

◆ Continue to Monitor and Update the Run Chart and Report Team Progress

HOW TO'S

- Brainstorm as many ways as possible to improve; invite additional ideas from individuals outside of the team.
- Identify the *best solution* – try using a solution selection matrix and/or force-field analysis.
- Identify the actions needed to implement the solution (i.e., staff training, preparation of supplies, etc.).
- Agree on a plan to accomplish the solution and include everyone affected by the improvement effort in the implementation process.
- Suggest criteria for evaluating how well the solution worked; divide the implementation effort into manageable steps for easier monitoring.
- Agree on a plan to accomplish the evaluation.
- Establish a time line for the improvement trial.
- Implement the improvement trial.

Step Five has been concerned with the Plan and Do phases of the PDCA cycle; the Check and Act portions will be completed in Steps Six and Seven.

* Template for this page available in Appendix.

CHECKLIST FOR STEP 5*

At the end of Step Five the team should have accomplished the following activities and reached consensus on the answers to the following questions:

- ☑ Brainstormed as many solutions as possible.
  Did we fully explore divergent opinions?
- ☑ Identified a best solution.
  Did we gain consensus without pressuring?
- ☑ Identified the actions needed to implement the solution.
  Do our plans include assignment of responsibilities and due dates?
- ☑ Developed an evaluation plan which includes criteria for evaluating the trial and time lines.
  Have we developed an evaluation plan to determine to what extent the desired state has been achieved?
- ☑ Implemented the trial.
- ☑ Monitored the process.
  Are we continuing to monitor the process and update the run chart?
- ☑ Reported progress.
  Have we updated our progress report?

OBJECTIVE

Evaluate The Improvement Trial

ACTIVITIES

- Evaluate improvement trial using established criteria.
- Compare results with the *desired state* from Step Two.
- Check for and address new problems created by the solution.
- Inform management of trial results so that change can be implemented systemwide (Step Seven), or return to Steps Three and Four to search for other sources of variation and/or to Step Five for root causes.
- Continue to monitor process with run chart.
- Continue progress report (storyboard/storybook).

DISCUSSION POINTS

In Step Five, your team planned and implemented an improvement trial. In Steps Six and Seven, the team enters the *Check* and *Act* phases of the PDCA Cycle.

The Check phase is a time of evaluation. As the team monitors and studies the changes that are taking place (using the criteria established in Step Five), what has the team learned? Did the original outcome (performance indicator) improve?

Act on the information. This last phase of the PDCA cycle is a time of decision making. Generally, the choices are:

- Act to *hold the gains* (make systemwide changes in response to the successful improvement trial).
- Investigate reasons for trial failure. (Assume that this improvement effort did not address the primary root cause and return to Step Four.)
- Abandon trial improvement efforts and go back to initial process analysis in Step Two.

Management must be involved in making this decision.

◆ Evaluate Improvement Trial Using Established Criteria

After carefully planning the improvement, implementation should be a relatively straightforward step. It is, however, in the bridge between planning and implementation where so many apparently *good* solutions fail. A review of some common pitfalls may be helpful.

- *Assumptions are weak.*

  Too often our assumptions about time are optimistic, those about resource requirements are inadequate, and those about commitment of others are unrealistic. Planning must be pragmatic, and this means the set of assumptions must be as realistic as is possible.

- *Contingency planning is not done.*
  If a plan is based on a single set of circumstances or conditions, it is extremely vulnerable to any change in those circumstances. Therefore, contingency plans are helpful to support the basic plans and to prepare for any possible, if unexpected, major changes. If possible, contingency plans should be developed to cope with both favorable as well as adverse changes. If implementation is broken into a number of sequential phases, for example, you must be as ready to bring Phase Two forward because Phase One took less time than expected as you are to delay Phase Two if Phase One takes longer than predicted.

- *The plan is not properly updated or communicated.*
  Failure to update the plan is a common cause of its failure. Too often the creation of a plan is treated as an end unto itself. Once you have moved into the implementation phases, it is important to bear in mind the basic assumptions of the plan. If these need to be changed significantly it will be necessary to update the plan, not just on a contingency basis but possibly in a radical manner. If this is not done, the plan stands little chance of achieving its original target.

  Communication is also vital. If people are not aware of what is expected from them or of changes that will result from implementation, it is almost certain that the plan will fail. It is important to consider both what needs to be communicated as well as how it should be done. Is it enough that people are informed – in which case a written document may be as effective as a meeting – or do you need to consult or negotiate with them? Time must be allowed for the appropriate method to be employed.

- *The necessary commitment is not obtained.*
  There are two separate but related issues here: The first is gaining commitment initially – from senior management, key individuals and other affected groups. The second is maintaining that commitment in the face of changes and of competing activities for their time, interest and skills. A well-developed and clearly-defined commitment strategy can be one of the most important factors underpinning any planning activity.

Compare Results with the *Desired State* from Step Two

Time should be planned for the *improvement* to stabilize. That is, to ensure that the change is truly effective, it is important not to evaluate the change too soon. Sometimes change will take place because attention is being paid to the process – not necessarily because the change is effective.

When the team is comfortable that the improvement has had time to stabilize, analysis of the overall effects of the improvement plan should be made. *What have we learned?* It is important to observe the outcome performance indicator; but the team should also discuss other findings discovered through the trial improvement – i.e., did the improvement require new staff, new equipment, new laboratory services, etc.?

It is extremely important that the process be monitored as it was at the beginning (baseline data from Step Two). This can be accomplished by routinely updating the run chart. The time when the improvement trial is implemented should be highlighted on the x-axis. Are process changes having the desired effect on outcome? What does the data collected during the trial improvement show? Compare the results of the trial to the *desired state* in the opportunity statement developed in Step Two. The team should observe if the outcome changes in response to the improvement activity.

Check For and Address New Problems Created by the Solution

As the trial is evaluated, the team should determine if the change resulted in any new problems (for example, with the management of anemia, correction of iron stores and anemia may result in healthier patients who eat more and, consequently, need adjustments in their dialysis prescriptions). Are these new problems (if any) significant enough to bring to management's attention or can the team resolve them? The new problems will have to be addressed before going forward with implementing the solution systemwide.

Inform Management of Trial Results So That Change Can Be Implemented Systemwide (Step Seven), or Return to Steps Three and Four to Search For Other Sources of Variation and/or to Step Five for Root Causes

If the results of the initial process improvement plan are successful, the team should present the findings to top management so that the change can be instituted systemwide. Communication between management and the project team is critical throughout the project but particularly at this juncture. The decision to initiate systemwide *improvements*, based on a trial approach, should consider an *impact assessment* that involves financial, administrative, and/or staffing changes as well as clinical improvement strategies.

If the process changes do not demonstrate improvement in outcome, do not be discouraged. Many soundly devised and implemented quality improvement projects do not produce a demonstratable improvement on their own, but may uncover patterns or trends which have application to other quality improvement projects and should not be ignored. Findings which may not have been found useful to this project team may have relevance to the overall management of the facility and may become the seed for additional quality improvement activities.

If the trial is not successful, the project team needs to *negotiate* with management for additional time and resources to continue to search for root problems. Management may decide on an alternative approach such as changing team composition, employing outside consultants, or limiting the scope of the project.

Continue to Monitor the Process With a Run Chart and Record Team Progress

HOW TO'S

- Aggregate and analyze data collected.
- Compare with *desired state* in opportunity statement from Step Two.
- Check for new problems created by the solution.
- Address additional problems or reinvestigate causes as needed.
- Present results to management.
- Plan full implementation if successful or return to investigate other sources of problems.

CHECKLIST FOR STEP SIX *

* Template for this page available in Appendix.

At the end of Step Six the team should have accomplished the following activities and reached consensus on the answers to the following questions:

- ☑ Collected data according to the plan.

  Was the trial improvement carried out correctly?
  Did we do what we said we were going to do?

- ☑ Analyzed the data.

  Was the monitoring process adequate?

- ☑ Evaluated the solution.

  Did the process improve? Did we do it the right way?
  Did it make a difference?

- ☑ Checked for new problems created by the solution.

  Were new problems identified?

- ☑ Addressed new problems or causes as needed.

  What unexpected findings were present?

- ☑ Agreed that the trial improvement was successful.

  Are we ready to change the system?

- ☑ Agreed that the trial improvement was not successful.

  Do we have team commitment to recycle back to search for another root cause?

- ☑ Presented initial results to management for consideration of further action.

  Does management agree that the trial solution should be implemented systemwide?
  Does management agree that the project team should cycle back to continue to search for root causes?

- ☑ Continued to monitor the process.

  Are we continuing to monitor the process and update the run chart?

- ☑ Updated the progress report.

  Are we ready to report the results of this project to others?

NOTES

OBJECTIVE

ACT ON THE RESULTS

ACTIVITIES

- After consulting with management, act on results.
- Prepare to report results of project.

DISCUSSION POINTS

◆ Act on Results.

At the end of Step Six, the team should have evaluated the results of the improvement trial and discussed their initial findings with management. Now it is time to *Act* on the results.

If there is agreement to initiate systemwide change based on a successful trial improvement, a new plan will be needed to ensure that change takes place in an orderly and controlled fashion. Thought should be given to communicating to all concerned *when* the change will take place, *what* needs to change and *why*, and *how* – instructing staff in the new procedures/or protocols. Additionally, it is critically important to continue to monitor the process until both management and the project team are sure of process stability.

If the trial improvement has not been successful, management must guide the project team's next course of action – to continue to investigate reasons for pilot failure or to abandon a particular project. Management will, in time, oversee multiple quality improvement project teams and consideration must be given to the importance of the project to the organization's primary customers (patients and payers) and to its internal operational concerns. If a decision is made to continue to search for other root causes of variation, the project team will need a firm commitment from management for time and resources with which to continue their work.

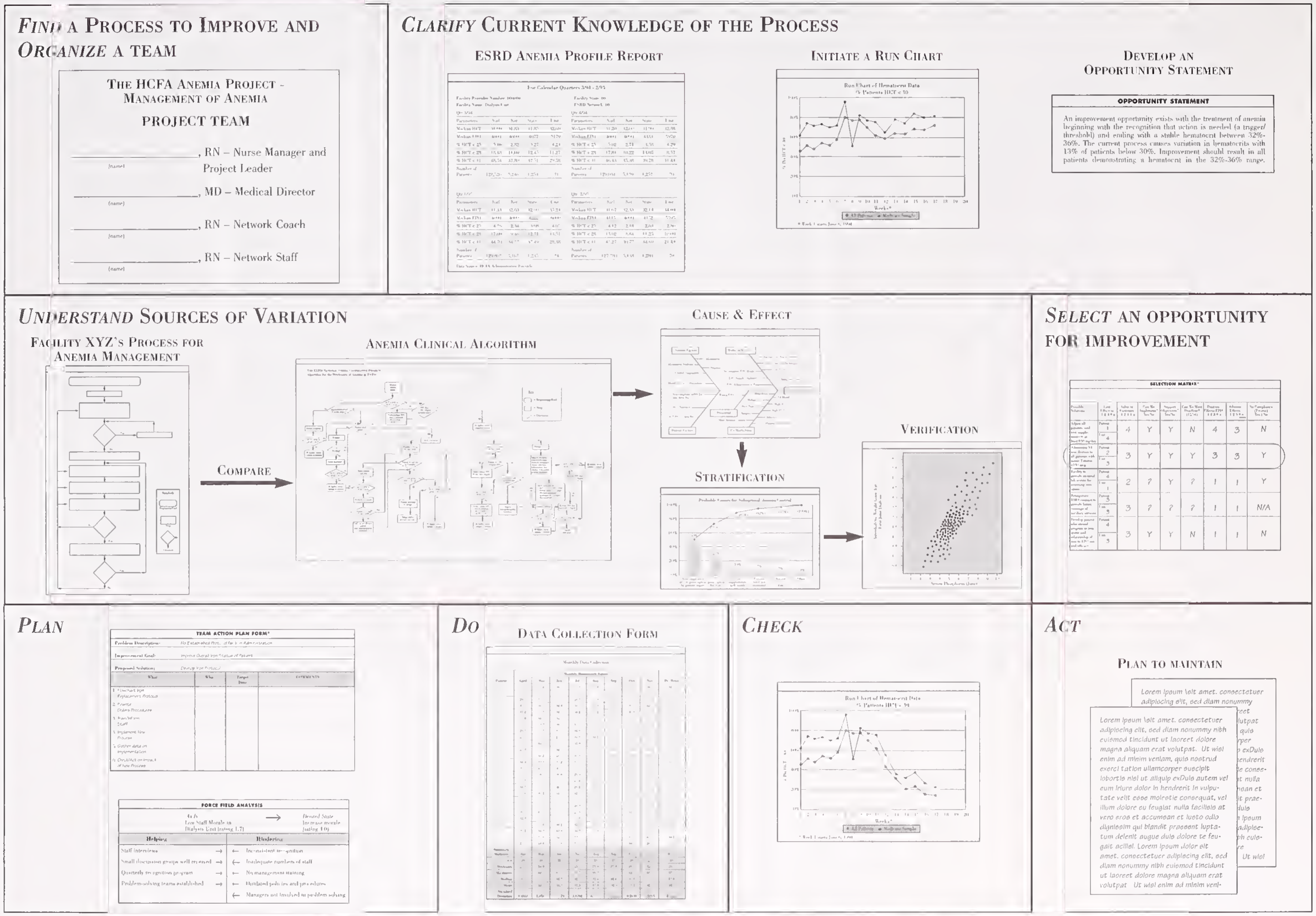
◆ Prepare to Report Results of Project

Reporting team progress is listed as the last task in each of the Seven Steps described in this Guide. Traditional minutes and/or progress reports are perfectly acceptable reporting mechanisms or perhaps your facility has a quality activity reporting form already in use. If not, you may wish to try a technique known as *quality improvement storytelling*, which usually involves a storyboard (*Fig. #25*) and or a storybook.[20]

20. *Hospitalwide Quality Technology Network*. Nashville, TN: Hospital Corporation of America; 1991.

Fig. 25 **STORYBOARD***

Example of FOCUS-PDCA Storyboard Using Graphics



* Template available in Appendix.

Telling the story of the quality improvement team is a worthwhile activity as well as a powerful teaching method. Many organizations and industries have used these techniques to relate the progress of quality improvement teams.

A **Storyboard** is used to display (formally or informally) the team's work as it is in progress. Although team members benefit from the storyboard, other individuals (physicians, patients, other clinicians, administration) interested in learning about the team's activities, are the primary customers. Storyboards vary in size (i.e., 30" by 40") and can be posted in the staff lounge or other highly frequented areas.

The layout of the storyboard generally parallels the improvement approach chosen (i.e., FOCUS PDCA, PDCA, Seven Steps) which helps the team organize their work for the benefit of teaching others. Storyboards should be attractive, visual instruments which display the team's progress, either graphically or in narrative form.

Each phase of the chosen improvement cycle/approach is summarized on the storyboard as it is completed. The board can be temporarily updated between team meetings and usually one team member is assigned the responsibility of updating the storyboard (perhaps the recorder).

The **Storybook** simply complements the storyboard by providing a more detailed version of the team's activities. The storybook includes minutes from team meetings, raw data, discussions from data analysis sessions, etc. The storybook can serve as the complete record of the team's activities. A storybook can be copied, distributed and used to:

- Report team activities in detail.
- Share quality improvement stories (successes as well as failures).
- Justify a team recommendation to management.

Other quality improvement teams can learn from your successes as well as your failures. Further, if the team's improvement action requires management approval, the storybook documents the basis of the team's decision by providing all the data considered in each step of the decision making process.

HOW TO'S

- If trial is successful, plan for systemwide implementation.
- If trial was not successful, plan next steps by considering the following:
  - Should other sources of process variation and their root causes be investigated?
  - Should the project team continue with the same members?
  - Does management support continued investigation into this process?
  - What other resources may be needed to continue process investigation?
  - What lessons have been learned thus far?
- Whatever the results thus far, share them with the staff. Choose a method of communication that will be most effective for your particular setting.
- If needed, seek advice from the Quality Managers at the ESRD Network Office.

One final note. The activities of the Project Team will be completed after implementing systemwide change and reporting results; however, the quality improvement cycle does not end. Action must be planned and implemented to *hold the gain*. Monitoring of performance measures must continue with regular review to ensure that improvements made are sustained. Additionally, future changes (man, machine, materials, methods) may introduce variability into the process, which will be apparent as the data are collected and displayed over time. *Holding the gain* may be the most challenging element of quality management since merely observing a process may cause behavior changes, and performance may revert back to previous habits as the intense observation subsides.

How long do we have to monitor this? This is a frequently asked question whose answer speaks to a true understanding of quality management principles. Monitor as long as the measure remains an important indicator of performance and is important to your customers.

* Template for this page available in Appendix.

CHECKLIST FOR STEP SEVEN*

At the end of Step Seven, the team should have accomplished the following activities and reached consensus on answers to the following questions:

- ☑ Acted on results, after consulting management.

  Has management agreed to implement and support systemwide change?

  Do all members of the project team agree to return to search for other sources and root causes of process variation?

- ☑ Prepared a report of the results of the project.

  Have all team members participated in preparing the report?

- ☑ Communicated results.

  Have the results been communicated to all staff?

This concludes the *ROADMAP to Improvement* for the Anemia Cooperative Project. Thank you very much for taking part in this unique project. Your participation is of critical importance to the success of this endeavor and your contributions will help to mold future approaches to managing and measuring quality in the Medicare End Stage Renal Disease Program.

INTRODUCTION

In this section, you will be exposed to key teaming tools and techniques recommended in the RoadMap. Many resources are now available which explain in far greater detail how to tailor data gathering and analysis to your particular setting. The descriptions provided in this section are purposely brief and provided primarily to increase awareness of quality tools and techniques. Readers are *strongly* encouraged to consult the references and sources used in the preparation of this Guide, particularly the following:

Recommended Reading

- Brassard M, Ritter D. *The Team Memory Jogger Plus: Featuring the Seven Management and Planning Tools.* GOAL/QPC; 1989.
- *Guide to Quality Management.* 5th ed. Skokie, IL: National Association for Healthcare Quality.
- Ott L. *An Introduction to Statistical Methods and Data Analysis.* Boston, MA: PWS-Kent Publishing Co; 1988. ISBN 0-534-91926-X
- Longo DR, Bohr D. *Quantitative Methods in Quality Management, A Guide for Practitioners.* American Hospital Publishing, Inc 1991. ISBN 1-55648-060-1
- Goldfield N, Pine M, Pine J. *Measuring and Managing Health Care Quality.* Gaithersburg, MD: Aspen Publishers Inc; 1994. ISBN: 0-8342-0265-4

Organizations to Contact for Additional Information

- Joint Commission on Accreditation of Healthcare Organizations
  One Renaissance Boulevard, Oakbrook Terrace, IL 60181
  Phone: (708) 916-5800
- GOAL/QPC
  13 Branch Street, Methuen, MA 01844-1953
  Phone: (800)643-4316 or (508) 685-6370, Fax: (508) 685-6151
- The Institute for Healthcare Quality
  135 Francis Street, Boston, MA 02215
  Phone: (617) 754-4800, Fax: (617) 754-4848

TEAMS AND TEAMING

TEAMS AND TEAMING

Putting together an effective team is an essential element in the quality improvement process. The goal of *teaming* is to produce as many perspectives about a problem or plan as possible and to use a systematic approach to resolve the issues. Membership is dictated by the nature of the process to be improved. People who work closely with the process, or groups likely to be affected by it, should have representative members. Membership will often cross divisional boundaries to accomplish this representation and will include people of different rank, profession, shifts or work areas. Group sizes over 15 are considered difficult to work with and the best group size is considered to be five to ten members.

Goals and Rules

Why work in teams?

Teamwork

- Builds communication down, through, across and up the organization.
- Fosters cooperation among individuals and groups.
- Provides consistency of effort.
- Stimulates innovation.
- Shares responsibility for decisions and recommendations.

In Quality-Focused Organizations

- All employees become knowledgeable about and are involved in continuous improvement activities. Employees are the ones who *work in* the processes, and the ones best suited to study and identify problems, and recommend solutions.
- Everyone contributes both individually and collectively through teamwork.
- A structure exists to link team efforts with top management.
- Cross-functional goals (such as quality, cost, schedules, mission, need, and suitability) are satisfied, with multidisciplinary teams becoming a goal of management.

In Pursuing Quality Improvement, Teams Are Encouraged to Stick to Four Basic Principles

- Develop a strong customer focus.
- Continually improve *all* processes.
- Involve employees.
- Mobilize both data and team knowledge to improve decision making.

Roles and Responsibilities

Management's Role

The quality environment requires investment in people, the largest and most valuable asset in an organization, because they are the most essential component in continuous process improvement. Therefore, a major focus of management activity is to nurture and support employee involvement in quality. All staff must be trained in the concepts of process thinking, assisted and coached in the development of teams and projects, supported by allocations of time and resources, and celebrated for their accomplishments.

Usually, management selects or approves team projects, negotiates with the team for resource allocations, recognizes or appoints a team leader, encourages the use of a standardized method for process investigation and improvement, and monitors team progress.

Training for quality improvement should include both quality concepts and techniques, such as statistical thinking and team building. To have an effective team, individuals must learn the importance of:

- Communicating openly and nondefensively.
- Listening attentively.
- Demonstrating respect and trust for each other, confidence in each other's abilities, and support for one another.
- Allowing and encouraging equal participation and sharing of ideas, including expression of dissenting views.
- Confronting conflicts and problems and using disagreement and conflict constructively.
- Being skillful in decision making and problem solving.
- Building consensus. Decisions must be understood and supported by all members of the team.

Additional attributes of ideal teams include the qualities listed below.

- Believe in and are committed to the value of working together in a spirit of cooperation.
- Understand the overall objectives of the organization.
- Understand individual roles and responsibilities as well as relationships to other staff members.
- Define and agree upon meaningful and measurable objectives that meet both group and personal needs. Individuality and creativity are not stifled.
- Members function well in a variety of team roles and know when appropriate roles are needed.

Team Roles and Responsibilities

To be effective and organized, each team must function within an administrative framework that supports the team's activities, services, and resources, gives authority to the team's work and grants the team its mission. Whatever organizational framework is used, certain roles and responsibilities are needed.

Team Leader

The team leader is an individual who is:

- Knowledgeable and interested in improving the process.
- Able to promote process changes.
- Capable of maintaining the momentum needed to keep the group moving forward.

This role can be taken by anyone on the team and may be traded during the course of a project. Duties of the team leader include:

- Keeping team discussions moving forward along the allotted time frames.
- Pulling the group together if discussion fragments into multiple conversations.
- Encouraging or pulling input from quiet members.
- Preventing domination by one group member.
- Checking for consensus on group decisions.
- Participating in decision making.

Team Coordinator

The team coordinator is a member who coordinates information and resources with the overseeing body of the team (management or the source of the team's authority and resources). This person also coordinates (*or delegates to another*) the logistical details for the team, such as meeting dates, times, etc. Smaller teams may choose to blend these tasks into other roles.

Facilitator (Quality Coach)

The facilitator role should be an objective one, with no ownership of the process. (Often coaches are totally unfamiliar with the process being studied.)

Facilitator tasks may include the following:

- Directing the *process* of the meetings.
- Keeping the team focused.
- Conducting training as appropriate.
- Providing expertise in quality management and/or process improvement techniques.

The facilitator *does not:*

- Deal with content unless permission of team members is given.
- Participate in decision making.

Recorder

This person keeps the written record of all team activities and is responsible for agendas, minutes, securing needed documents for the team, and updating the storybook and/or storyboard. This assignment can be rotated among team members so as not to overburden any one individual. The recorder is included in brainstorming sessions by either taking his or her turn (round robin) or waiting until late in the session (free wheeling) to add ideas to the list.

Timekeeper

Most teams face time constraints. To help teams manage their time effectively, the group should agree upon allocations of time for agenda items. The timekeeper is assigned responsibility for:

- Leading the initial discussion to allocate time to the agenda.
- Monitoring how long the group is taking to accomplish its tasks.
- Giving regular updates to make group members aware of where they are.

The timekeeper notifies the team when time runs out and the group decides whether or not to continue. The team may decide to reallocate its time as the agenda progresses. It may even decide not to complete the task within the time limit. These are group decisions, not the timekeeper's individual choice.

Team Members

Each member plans responsibility for what happens in the group, sets ground rules, and takes responsibility for and participates in the group activities. Members have duties as assigned by the team leader.

Consultants

Consultants may be asked to join when the team reaches an area for which they need additional or outside expertise on a limited basis.

Project consultants may be able to help with the technical expertise concerning certain aspects of the process under study. They may be from internal sources such as pharmacy, billing departments, other attending physicians, or external sources, such as industry, the Networks, or neighboring health agencies.

Quality consultants may assist the team with technical expertise in the scientific problem-solving process and the use of CQI tools and techniques. Examples include statisticians, data managers, quality management professionals, Network Quality Managers, etc.

Ground Rules

Within every effective group, certain rules are agreed upon by the team members. These rules may address, but are not limited to, the issues listed below:

- Decision making belongs to the entire team. What will be the policy or procedure for reaching consensus in decision making?
- What are legitimate reasons for missing a meeting or arriving late? Attendance should be a high priority for the team.
- Agree upon a regular meeting time, day and place, and decide on frequency of the meetings. The team may revisit the schedule at different times during the project.
- Agree on giving every member an opportunity to contribute and to be listened to with respect.
- Agree to disagree openly and debate differences in points of view.
- Agree to timely completion of all assignments so the group is not delayed by any individual member.
- Discuss any other ground rules your group finds necessary such as break frequency, smoking, language, etc.

Team Training

Quality improvement integrates statistical thinking and management actions and provides managers with the facts necessary for data-based decision making. Managers do not have to rely on instinct or intuition to make decisions because quantitative methods are used to:

- Identify problems, not symptoms or signals.
- Demonstrate the effectiveness of solutions.
- Monitor the progress of improvement.

Managers and employees alike will need to develop *skills* in the use of CQI tools and techniques to enable them to scientifically study and constantly improve every process by which work is accomplished. Many new educational resources are now available to support employee training and should be consulted in designing individual training programs within organizations.

A myriad of books, journal articles, videos and other educational materials are available to facilitate staff training in quality improvement philosophy, tools and techniques. The organizations listed at the end of this section may be contacted for a list or catalog of resources.

In addition, your local ESRD Networks can serve as a valuable resource for quality improvement guidance and information. Networks have quality personnel on staff and many Networks conduct regional workshops. Another resource you may wish to consider is a local community college. Many of these institutions, particularly in industrial areas, offer *short courses* in quality-related topics such as team facilitation, control charts, benchmarking, process control and more.

SUMMARY

Team Member Roles

Members

- Participate and assist in making meetings successful.
- Keep facilitator and/or leader on track.
- Let facilitator know when they have touched content without permission.
- Let recorder know if something is not recorded or is recorded incorrectly.
- Participate in decision making.
- These are the people closest to the process being examined.

Leader

- *Owner* of the process.
- Keeps group on track by directing content of the meetings.
- Deals with adverse group behaviors.
- Participates in decision making.

Recorder

- Helps team maintain records.
- Accurately records all activities and decisions on flip chart so they can be viewed by all.
- Receives an *okay* from members if rewording is necessary.

Facilitator (Could Also Be Quality Coach)

- Directs the process of the meeting.
- Keeps team focused.
- Has expertise in quality management and process improvement.
- Conducts training as appropriate.
- Does *not* deal with content unless permission of team members is given.
- Does *not* participate in decision making.

Consultant

- Provides insight and/or advice to group based on area of expertise.
- Does *not* participate in decision making.

Coordinator

- Coordinates and schedules meetings and related activities.
- Coordinates between-meeting activities which include inviting additional members and consultants to attend future meetings as agreed upon by the team.

Timekeeper

- Helps team manage time *during* meetings.

TOOLS

TOOLS

This section offers a brief description of key tools that support the analysis and graphic display of data. Though often intimidating at first, these tools are actually extremely simple to use and produce amazingly powerful results.

Control charts and *run charts* are central to process improvement because of their use in describing how the process performs over time. These tools are used to gain understanding of how well the process works in meeting customers' needs, to determine what kind of variation is present in a process (special cause or common cause), and to eliminate special cause variation (or bringing the process into statistical control).

Other tools presented in this section are used to describe a *snapshot* of data rather than data over time. Tools such as the *Pareto diagram, histogram,* and *scatterplot* are extremely useful for quickly and graphically communicating the shape and distribution of a data set.

Finally, *flow charts* and *cause-and-effect diagrams* are described. These two tools are designed to gather knowledge and data about the steps and components of a process. Data displayed on these tools may be qualitative and subjective rather than quantitative, but are valuable for process improvement.

No one tool can support an entire process improvement project; therefore, the *power base* for statistical thinking and decision making is formed when these eight tools are used in combination. Many team members will be reluctant at first to use these quality tools, believing that intensive math and/or computers are required. Actually, little more is needed than pencils, paper (graph paper is helpful), a ruler, and a calculator with scientific notation. Data displays may be hand drawn – computer graphics are not required (though many teams will choose to employ computers over time). Most tools require only simple math to determine averages or percentages and, if needed, consultants may be requested for developing control charts where *statistical significance* is required.

Templates for many of the tools are available in the Appendix. The templates are provided as a *guide;* your team may wish to modify them to better meet your goals.

CAUSE-AND-EFFECT ANALYSIS (FISHBONE DIAGRAM)

What Cause-and-Effect Analysis Is

Cause-and-effect analysis is a systematic way of exploring and displaying sources of variation in a process. The effect (outcome) can either be a problem (the *as is* statement of the situation you want to correct) or the desired state (what you want to exist when problems have been solved).

Purpose

- Enables a team to focus on the content of the problem, not on the history of the problem or differing personal interests of team members.
- Creates a snapshot of the collective knowledge and consensus of a team around a problem.
- Focuses the team on causes, not symptoms.

What Cause-and-Effect Analysis Looks Like

The diagram in its skeletal form resembles a *fishbone* and is frequently referred to by this name. The *effect* or outcome is placed in a box at the right side of the page (the head of the fish), and the causes are drawn as ribs off the backbone.

How to Construct

- Place the outcome, problem statement or desired state, on the right side of a large sheet of paper (the fish's head).
- Draw a horizontal line to the left of the effect.
- Use predetermined categories such as:
  - For technical problems: man, machine, materials, method, environment
  - For clinical problems: staff, patients, resources, policy, procedures

There is no perfect set or number of categories. Make them fit the problem.

Draw diagonal lines and place half of the categories above the line and half below the line. Brainstorm a list of process variables, then sort into the predetermined categories. List subcauses and place them under the main causes to show relationships among the causes.

Once the cause-and-effect diagram has been created, the next step is to identify those causes that have the strongest impact on the effect. This must be done by examining the cause-and-effect relationships. Gather additional data to verify the absence, presence, and magnitude of variables (Pareto diagrams, histograms) and the relationship of one variable to another (scatterplots).

When to Use Cause-and-Effect Analysis

Identify Sources of Problems

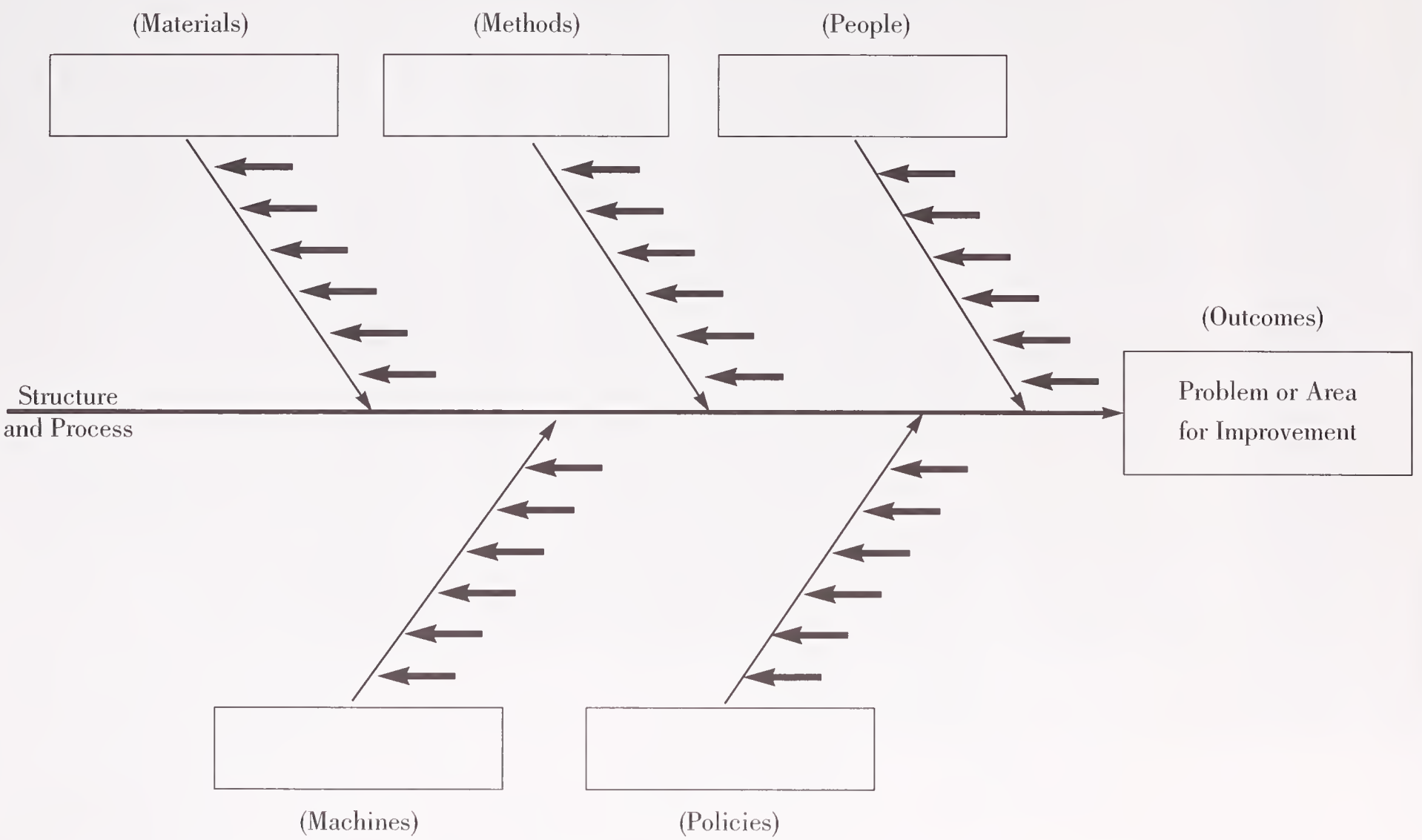
- In Steps Three and Four, to identify and verify the factors which are causing the variation (problems).

Planning

- In Step Six, to identify what factors must be present in order to implement the recommended solution successfully.

Fig. 11A

CAUSE-AND-EFFECT DIAGRAM – BLANK FORM*



* Template available in Appendix.

CHECKSHEETS

What Checksheets Are

Checksheets are forms designed to collect data and show how many times particular events (causes of variation) occur.

Purpose

- Collect data in a systematic and consistent manner.
- Assists in translating opinions into facts.
- Applicable to any key performance area.
- Forces agreement on definitions of each condition or event by searching for and recording the same thing.

How to Construct a Checksheet

- Agree and clearly define the objective of data collection.
- Determine other information about the subject of the data collection that should be recorded, such as shift, date, or machine. (This information may be needed later to further analyze or to stratify the data.)
- Determine and define all categories of data to be collected. (A specific and clear definition of each data category ensures that all collectors will gather consistent data. It is helpful to print any such *operational definitions* on the back of the form.)
- Decide who will collect the data, over what time period, and from what sources. Consider the effects of collecting data during particular months or on particular days of the week. If appropriate, select a sample size.
- Design and *pilot* test the form prior to formal data gathering.
- Distribute the checksheet and collect the data consistently and accurately.
- Tally all individual data sheets and develop appropriate data displays (scattergrams, Pareto diagrams, histograms, bar charts, tables, etc.).
- Evaluate the data.

Fig. 5 **CHECKSHEET - BASIC**

Checksheet for
Baseline Hematocrit Data Collection

Patient ID	Check if on EPO	_____ month HCT	_____ month HCT	_____ month HCT
Mean for all patients				
Mean for patients on EPO				
Mean for patients not on EPO				

* Template available in Appendix.

Fig. 26 **CHECKSHEET, MATRIX - COMPLETED WITH EXAMPLE OF AGGREGATE DATA**

Aggregate Data for Causes of Anemia

Patient Sample: All patients with HCT < 32% on two or more occasions between October 23-December 3, 1994

AGGREGATE			
Modality	HD	PD	ALL
Hematocrit	Mean	Median	Range
Imferon given			
Oral Fe preparation prescribed	-		
EPO Administration Time	before	end	after
EPO Route	SQ	IV	
CAUSES/FACTORS	# OCCURRENCES	% OF TOTAL	CUMULATIVE %
Methods/Materials	55	35.7%	35.7%
Co-Morbidities	49	31.8%	67.5%
Dialysis Factors	44	28.5%	96.1%
Patient Factors	5	3.2%	99.4%
Personnel	1	0.6%	100%
TOTAL ALL CAUSES (Pareto denominator)	154	100%	100%
Inadequate Dialysis ***	30	19.5%	19.5%
Inadequate Iron Replacement/Stores	28	18.2%	37.7%
EPO Dose Held or Reduced	18	11.7%	49.4%
↑ PTH	18	11.7%	61.0%
Clotted Disposable	14	9.1%	70.1%
Poor Nutrition	13	8.4%	78.6%
Surgery	11	7.1%	85.7%
EPO Supply Depleted	9	5.8%	91.6%
Infection/Inflammation	5	3.2%	94.8%
EPO < 3 months	4	2.6%	97.4%
Wrong Dose	1	0.6%	98.1%
Volume Expansion	1	0.6%	98.7%
GI Bleed	1	0.6%	99.4%
Platelet Dysfunction	1	0.6%	100%
TOTAL ALL CAUSES (Pareto denominator)	154	100%	100%

*** Inadequate Dialysis (30)
KT/V < 1.2 = 17
Missed Rx x 2 = 3
Rx < prescribed = 10
Missed Rx & low BFR reported several times in conjunction with low KT/V but were counted as BFR or missed Rx for more specificity.

Fig. 27 **CHECKSHEET, BASIC – COMPLETED**

National Anemia Cooperative Project
Spreadsheet Example of Monthly Data Collection

	Monthly Hematocrit Values								
Patient	**April**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Pt. Mean**
	35.0	35.2	34.5	33.8	31.2		37.0	36.9	34.8
	28.0	28.0	31.8	23.0		39.8	27.2		29.6
	29.1	31.6	31.1	28.3	28.3	31.8	27.9	31.2	29.9
	35.9	36.6	34.4	38.7	39.9	37.8	30.7	42.1	37.0
	31.2	31.3	32.7	34.2	37.2	29.9	30.4	27.0	31.7
	30.4	34.7	32.7	37.7	37.6	32.8	29.7	34.8	33.8
	31.0	33.3	39.1	33.7	29.3	34.9	33.9	34.4	33.7
	29.1	31.1	27.0	34.6	33.7	31.0	36.2	32.1	31.9
	27.7	29.0	27.7	32.6	34.1	29.0	30.8	28.	29.9
	38.7	42.1	35.1	32.4	32.3	33.7	29.7	37.0	35.1
	25.4	28.6	32.0	31.9	31.6	33.5	20.5	37.5	30.1
	35.7	36.2	28.0	30.8	36.2	36.2	42.7	23.7	33.7
	34.2	33.1	35.2	37.0	35.9	36.2	31.1	30.9	34.2
	30.5	28.9	30.1	35.5	27.7	32.6	31.0	29.1	30.7
	30.8	24.7	39.4	29.9	33.4	27.3	26.6	38.6	31.3
	31.5	33.0	33.0	29.4	30.5	28.9	33.8	31.9	31.5
	34.1	35.0	36.7	29.2	27.7	29.8	28.9	34.3	32.0
	31.6	30.1	32.7	32.5	31.2	31.4	28.3	36.9	31.8
	28.0	34.9		31.5	34.9	30.7	36.2	22.1	31.2
	29.5	31.1		26.3	21.8	35.0	28.2	30.9	29.0
	30.0	27.7		28.9	26.1	30.5	32.7	29.0	29.3
	32.3	31.5		33.2	27.0	37.1	32.9	38.6	33.2
	31.9	33.4	34.1	32.0	31.8	33.4	31.8	31.9	32.5
	30.1	34.3	43.6	34.7	30.4	32.7	27.8	32.3	33.2
	31.8	31.8	32.5	33.7	35.5	33.9	28.0	45.6	34.1
	21.7	24.2	29.6	33.5	29.8	33.0	34.8	26.8	29.2
Summary Statistics	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Mean
n =	26	26	22	26	25	25	26	25	26
Minimum	21.7	24.2	27.0	23.0	21.8	27.3	20.5	22.1	29.0
Maximum	38.7	42.1	43.6	38.7	39.9	39.8	42.7	45.6	37.0
Median	30.9	31.7	32.7	32.6	31.6	32.8	30.8	32.1	31.8
Mean	31.0	32.0	33.3	32.3	31.8	32.9	31.1	32.9	32.1
Standard Deviation	3.4853	3.8567	3.9779	3.4792	4.1616	3.0324	4.2939	5.5095	2.0963

* Template available in Appendix.

Fig. 16a **CHECKSHEET, MATRIX – BLANK FORM***

Checksheet for Causes of Anemia

Patient Sample: All patients with HCT < 32% on <u>two</u> or more occasions _____, 199__
(date)

FACTORS ↓ PATIENT ID→						AGGREGATE		
Modality						HD	PD	ALL
Hematocrit								
Dialysis Factors								
Inadequate Dialysis								
Clotted Disposable								
Blood Loss 2° Procedure								
Methods/Materials								
Inadequate Iron Replacement/Stores								
Imferon given								
Oral Fe preparation prescribed								
EPO Dose Held or Reduced								
Lab Error								
EPO Administration Time						before	end	after
EPO Supply Depleted								
EPO Route						SQ		IV
Personnel								
Wrong EPO Dose								
Patient Factors								
Volume Expansion								
On EPO < 3 Months								
Co-Morbidities								
Hemolysis								
GI Bleed								
Surgery								
Poor Nutrition								
Malignancy								
↑ Al +++								
↑ PTH								
Infection								
Platelet Dysfunction								
Other Anemia Causes (Hemoglobinopathy, B_{12}, Folate or Pyridoxine deficient)								

CONTROL CHARTS

What Control Charts Are

Control charts are run charts with statistically determined upper control limits (UCL) and lower control limits (LCL) drawn on either side of the process average.

Purpose

- Monitor, control and improve process performance over time.
- Distinguish *special* from *common* causes of variation.
- Guide management action.

Control limits are *not:* goals (what you want), specifications, wishes, thresholds, or budgets.

How to Construct a Control Chart

- Select the process to be charted.
- Determine sampling method and plan.
- Initiate data collection.
- Calculate the appropriate statistics.
- Calculate the control limits (need 20-25 data points).
- Construct the control chart.
- Analyze the control chart.
- Determine if the process is *in control.*

How to Use a Control Chart

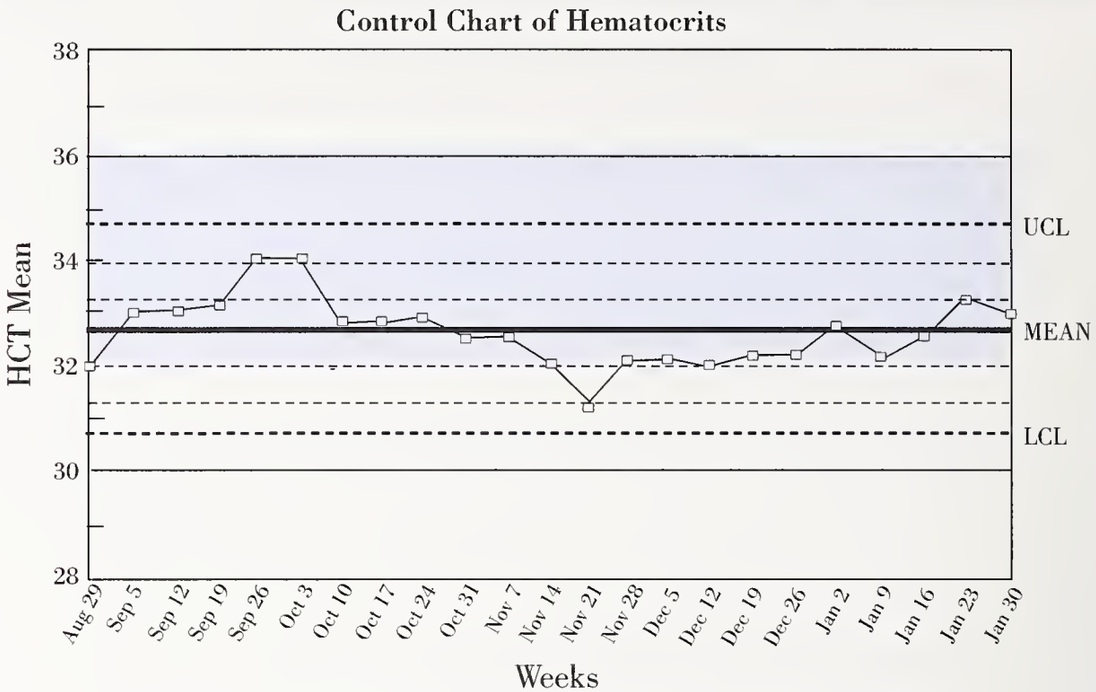
There are many types of statistical control charts. The control chart your team decides to use (an attribute or variables control chart) will determine what formula must be used.

A full discussion of control charts is beyond the scope of this Guide.

Suggested reading

1. Brassard M, Ritter D. *The Memory Jogger: A Pocket Guide for Team Members*. Methuen, MA: GOAL/QPC;1995.
2. Ott L. *An Introduction to Statistical Methods and Data Analysis.* Boston, MA: PWS-Kent Publishing; 1988. ISBN 0-534-91926-X.
3. Longo DR, Bohr D. *Quantitative Methods in Quality Management, A Guide for Practitioners*. American Hospital Publishing Inc; 1991. ISBN 1-55648-060-1
4. Finison LJ, et al. The use of control charts to improve health care quality. *Journal of Healthcare Quality*. February 1993;15:9-23.

Fig. 7 **CONTROL CHART**



Upper & Lower Control Limits (UCL & LCL) were set at ± 3 Standard Deviations
Shaded Area is Treatment Goal Range of 32 - 36

F

FLOW CHARTS

What Flow Charts Are

A flow chart is a graphic picture of the steps in a process that any product or service follows.

Purpose

They are used to examine the relation and sequence of steps to:

- Show redundancies, inefficiencies, misunderstandings, waiting loops, and inspection steps.
- Compare and contrast *actual* vs. *ideal* flow of a process.
- Allow team members to analyze work activities and their impact on process performance and variability.
- Use as a training aid.

What a Flow Chart Looks Like

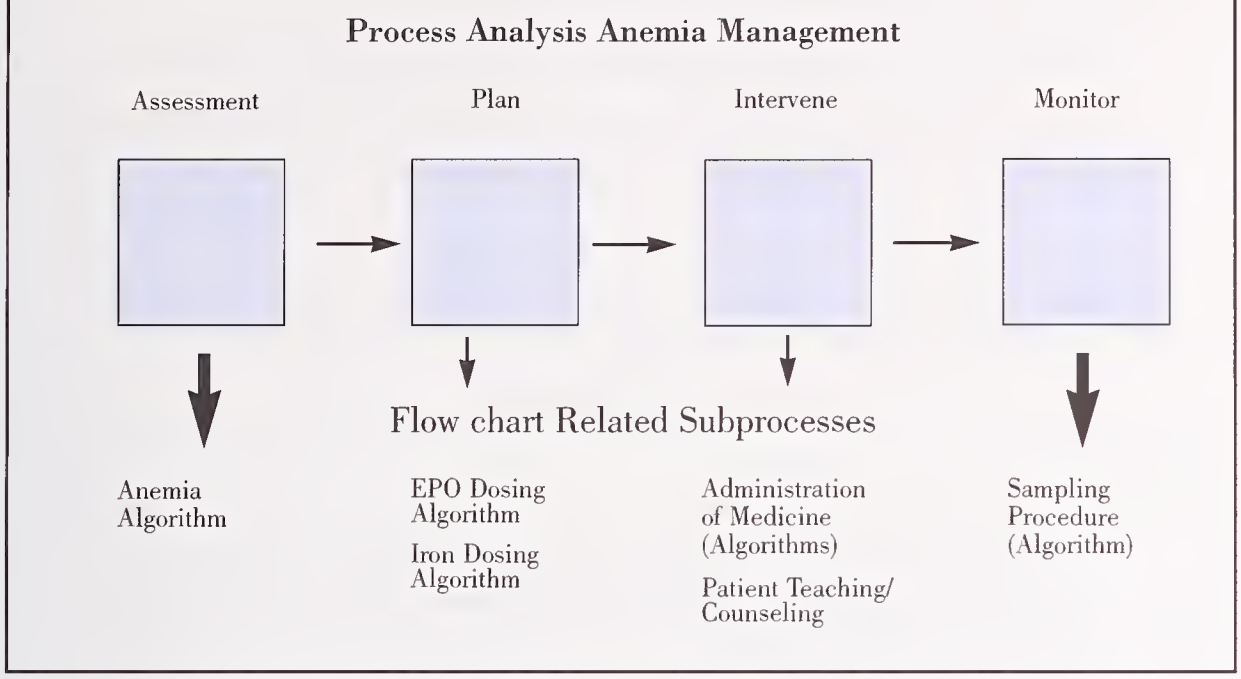
The flow chart can be a simple macro flow chart showing only sufficient information to understand the general process flow, or it might be detailed to show every finite action and decision point. The team might start out with a macro flow chart and then add in detail later or only where it is needed. (See *Figure 10* in Step Three for an example of a detailed flow chart.)

How to Construct

- Flow charts use standard, easily recognizable symbols connected by arrows to show how the work process operates.
- Decide on where the process starts (input) and ends (output) and the level of detail desired (process boundaries).
- Brainstorm to record all the activities and decision points involved in the process. The brainstorming should be done by those familiar with the various parts of the process.
- Sequence the steps.
- Draw the flow chart using the appropriate symbols.* Connect them with lines and arrows to indicate the flow or direction of the process.
  - An oval is used to show the materials, information or action to *start* the process or to show the results at the *end* of the process.
  - A box or rectangle is used to show a task or activity performed in the process.
  - A diamond shows those points in the process where a yes/no question is being asked or a decision is required.
  - A circle with either a letter or a number identifies a break in the flow chart and is continued elsewhere on the same page or another page.

  *Additional symbols can be used if greater detail and/or complexity is desired but the four symbols described above are generally sufficient.
- Test the flow chart for completeness; ask other staff to review.
- Analyze the flow chart.

Fig. 12 **TOP-DOWN FLOW CHART**



HISTOGRAMS

What a Histogram Is

A histogram is a graphic summary of variation in a set of data showing the distribution of that variation. Because of its immediate visual impact, a histogram is more effective for displaying data than a checksheet or frequency table.

What a Histogram Looks Like

Summarized data is organized into columns or *bars* and presented in graph form (an *x/y bar chart*) to display distribution.

How to Construct a Histogram

- Arrange the data to be plotted in order from smallest to largest. (In general, it is helpful to have at least 25 data points for a histogram. This ensures that at least five bars can be used to obtain a reasonable *picture* of the data.)
- Calculate the range of the data by subtracting the smallest value from the largest.
- Determine the approximate number of bars to display on the histogram. (*This is equal to the square root of the number of the data points, rounded to the nearest whole number.*)
- Calculate the width of the bars by dividing the range by the number of bars and rounding to the closest unit of measure being used.
- Set the upper and lower bounds for each bar by starting at the lowest value of the data and successively adding the bar width. *(To prevent data from falling on the bounds, subtract one half the unit of measure from the lowest value before adding the bar width to calculate the remaining bounds.)*
- Draw and scale a vertical axis to show the number of times a value of the data falls within each bar and a horizontal axis to show the beginning and ending bounds for each bar.
- Starting at the left side, draw bars with heights equal to the number of times the data falls within the bounds of each bar.
- Compare the results of your histogram to your customer requirements or specifications. Is the histogram centered on the process target and within the specification limits (upper and lower control limits)?
- Title the histogram and note the source, data, and data collector(s).

When to Use Histograms

- In Step Two, to illustrate the distribution of data and describe the current process performance – e.g., percent of patients with hematocrits below 24%, percent between 24% and 27%, percent between 28% and 30%, percent between 31% and 36%, percent above 36%.
- In Step Three, to display data collected related to potential causes of variation.
- In Step Seven, to display data collected to evaluate effectiveness of implemented solution – *moving the curve* toward quality improvement.

Analysis of Histograms

What is the shape? The shape of the histogram provides information such as the most common value of the variable, how great the data's spread or dispersion is, whether the data are symmetric or skewed, or if there are extreme data values.

HISTOGRAM PATTERN INTERPRETATION

Normal Distribution

- Centered and well within customer limits.
- Maintain present state.

Bimodal (Twin-Peaks)

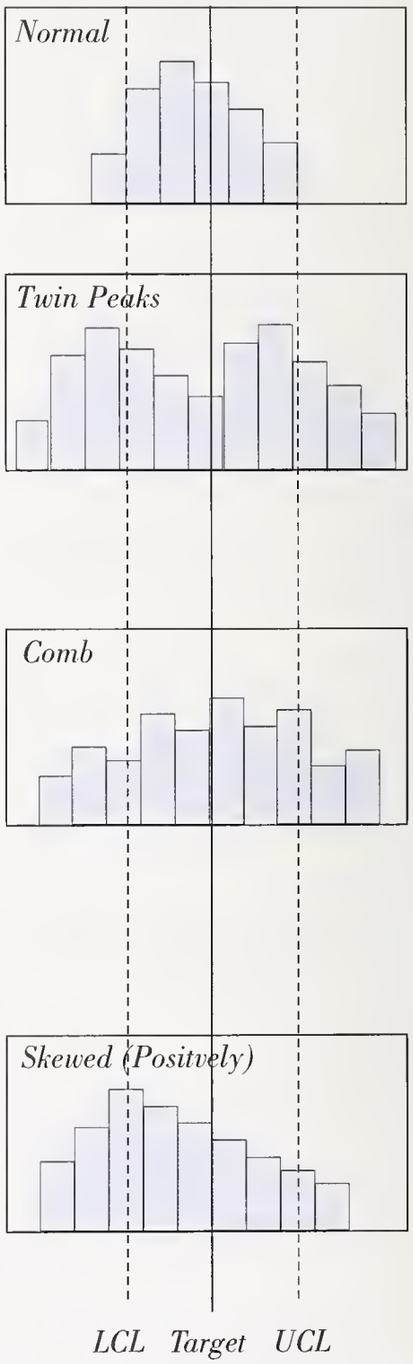
- There appear to be two peaks of high frequency in this shape indicating that the data are coming from two or more different sources – e.g., shifts, machines, people, suppliers. If this is evident, stratify the data.

Multimodal (Comb)

- Note that every other class has a low frequency when compared to its neighbors. This shape can occur when the data were rounded off inconsistently.
- Check the raw data and review the data collection plan for rounding instructions.

Skewed (Low)

- Process is running low.
- Defective product/service.
- Bring average closer to target.



PARETO ANALYSIS

What Pareto Analysis Is

A Pareto diagram prioritizes causes of variation (factors in a process) by displaying those characteristics in descending order of occurrence.

Purpose

- Focus efforts on problems that offer the greatest potential for improvement.
- Illustrate relative frequency or size of characteristics in a descending bar graph.

Pareto analysis is a technique that separates the *vital few* from the *trivial many.*

Named for Vilfredo Pareto, a 19th century economist who worked with income and other unequal distributions, the familiar 80-20 rule (*80% of our business comes from 20% of our customers*) is an example of Pareto analysis.

What a Pareto Diagram Looks Like

Like the histogram, a Pareto diagram is a bar graph showing distribution; however, in this case data are ranked and arranged in descending order. Analysis of the diagram should draw attention to problems (or causes) which are the greatest problems, thereby enabling a group to set priorities.

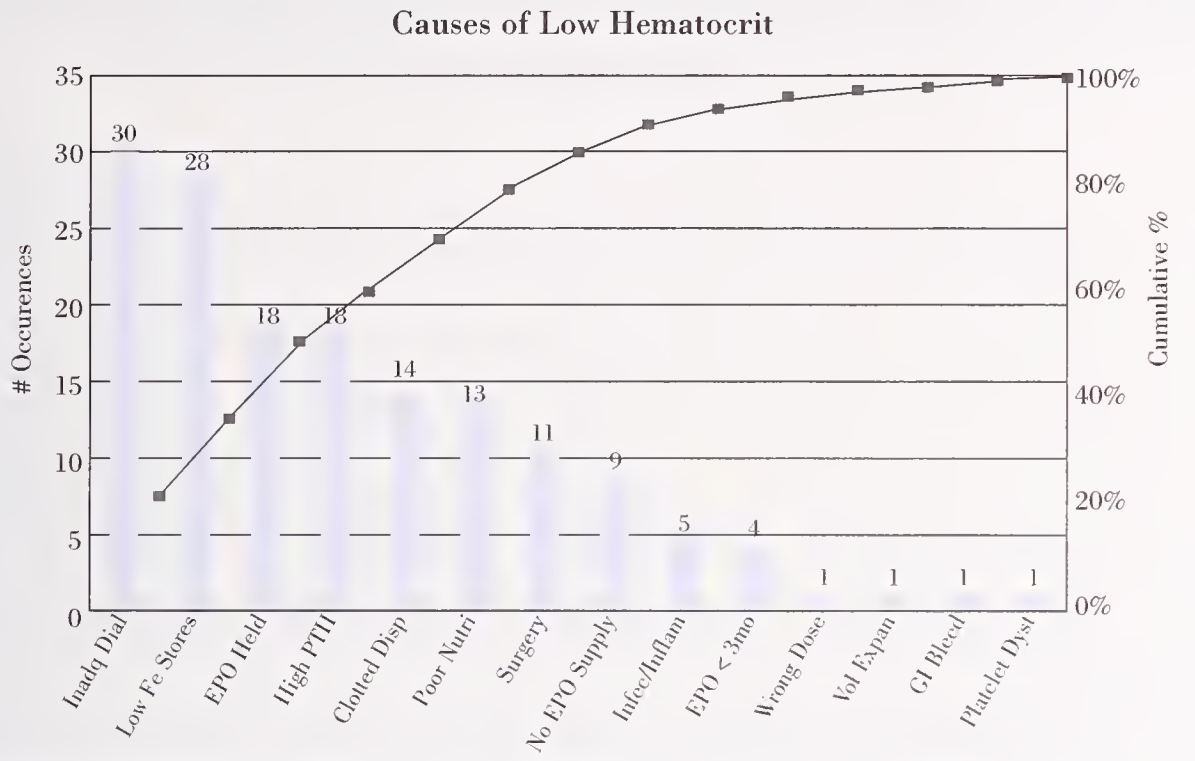
Pareto diagrams may be used with or without a cumulative line. When cumulative lines are used, they represent the percentage sum of the vertical bars, as if they were stacked on each other going from left to right. The cumulative line helps to illustrate the concept that *80% of the current problem* comes from *20% of the causes.*

How to Make a Pareto Diagram

- Decide which problem you want to know more about.
- Select the type of causes or conditions to be compared. The team must choose the specific factors contributing to the outcome.
- Determine the unit of measurement for comparison – this could be frequency, cost, or time.
- Choose a time period for the study and use a checksheet to collect the required data.
- Arrange the data in order from largest category to smallest.
- Calculate the total.
- Compute the percent of the total that each category represents.
- Compute the cumulative percentage for each category with all previous categories.
- Draw and label the left vertical axis with the unit of comparison. Scale this axis from zero to the grand total of all categories.
- Draw and label the horizontal axis with the categories, largest to smallest, left to right.
- Working from left to right, construct a bar for each category, with height indicating the frequency (not percentage). Start with the largest category and add them in descending order.
- Draw a vertical scale on the right of the graph, and add percent scale (0% to 100%).
- Draw a line graph of the cumulative percentage, beginning with the lower left corner of the largest category (the *zero* point).
- Title the Pareto diagram and note the source of the data, date, and data collector.

Fig. 17

PARETO ANALYSIS



Based on data from 45 HD patients w/ HCT < 32 on 2 or more occasions between 10/23/94 & 11/28/94

Fig. 28 **PARETO WORKSHEET – BLANK FORM ***

Causes/Factors	# Occurrences	% of Total	Cumulative %
Total of All Causes (denominator)			

* Template available in Appendix

RUN CHARTS

What a Run Chart Is

A run chart displays data variables over time.

Purpose

- Displays process variation and can be used to indicate special causes of process variation in the form of trends, shifts, or other nonrandom patterns.
- Compares a performance measure before and after implementation of a solution to measure its impact.

How to Construct a Run Chart

- Decide on what data will be collected and over what period of time. If the data are already collected, the team will have to decide which data to display.
- Draw a graph; the horizontal (x) axis indicates the time or sequence and the vertical (y) axis indicates the increments of measure (e.g., a process variable or the key process outcome such as the hematocrit).
- Plot the data points (median for the population) from the designated time period on the graph; connect the points with a line. A graph is often used to begin to observe data over time. However, if the graph is to be used to analyze variation, a mean or median should be added.
- Calculate the mean of the plotted numbers and draw a mean line on the graph. (The mean or average is the sum of the measured values divided by the number of data points. The mean is the most frequently used measure of the *centering* of the sample. Is the mean where it should be relative to customer need or specification?)
- Title the chart and note the source of the data, date, and data collector.
- Interpret the run chart.

Analysis of a Run Chart

Evaluate the run chart to identify meaningful trends, shifts, or patterns. A danger in using a run chart is the tendency to see every variation in the data as being important. The following guidelines may be useful in detecting the presence or absence of special causes of variation. Generally, detecting signals of special cause variation requires multiple data points on a run chart. To detect special cause signals in a shorter duration of time, a control chart is needed.

Trends

Trends are indicative of a changing process. Look for six lines between seven consecutive points all going up or all going down. If the value of two or more consecutive points is the same, include them individually in the calculations. Like values do not make or break a trend.

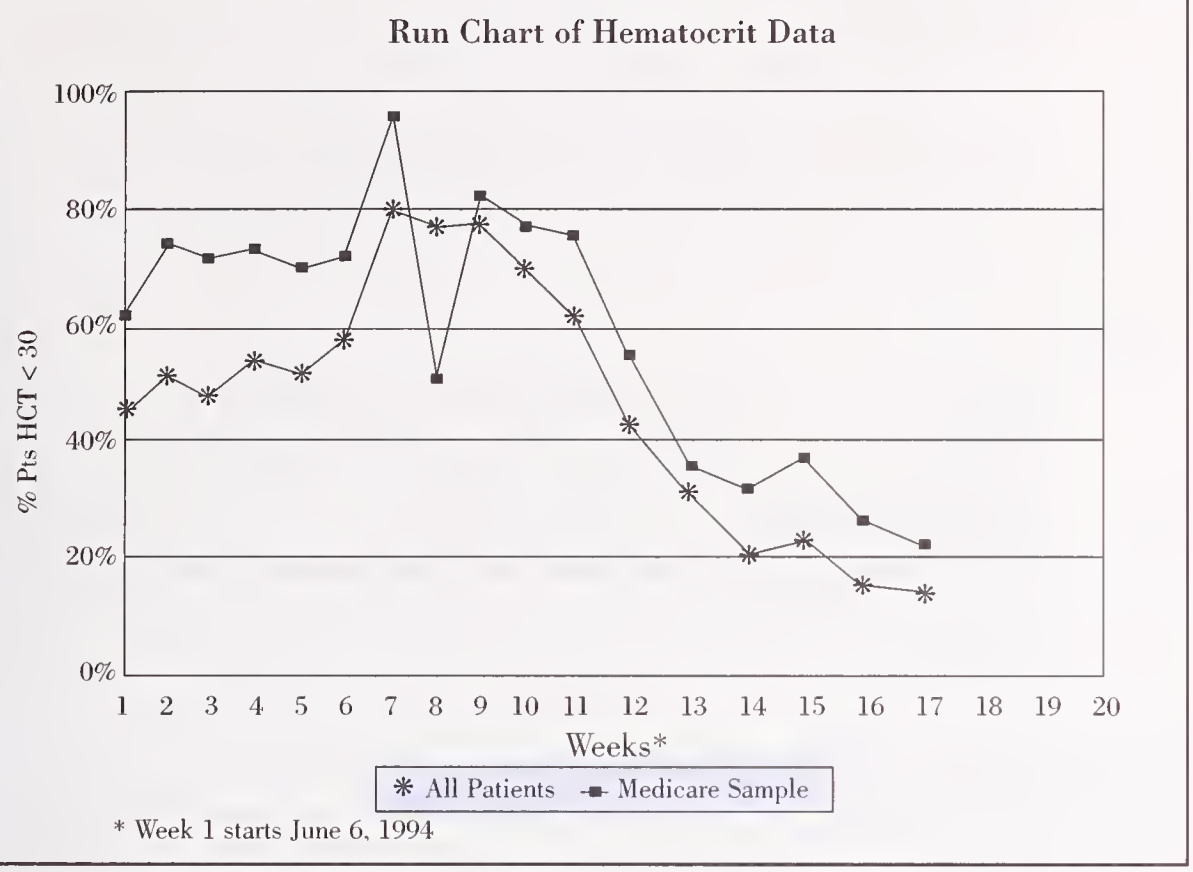
Shifts

Look for eight or more consecutive points running either above or below the center line (mean).

Patterns

Any nonrandom pattern may be an indication of a special cause of variation. Investigate any nonrandom pattern that recurs eight or more consecutive times.

Fig. 6 **RUN CHART**



SCATTERPLOT

What a Scatterplot Is

A scatterplot or diagram is a graph of data used to uncover evidence of whether or not a relationship exists between two factors. These factors could be a key quality characteristic (process outcome or *effect*) and a process variable (cause).

Purpose

- Supplies the data to confirm a hypothesis that two variables are related.
- Provides both a visual and a statistical means to test the strength of a potential relationship.
- Provides a good follow-up to a cause-and-effect diagram to find out if there is more than just a consensus connection between the causes and the effect.

How to Construct a Scatterplot (Diagram)

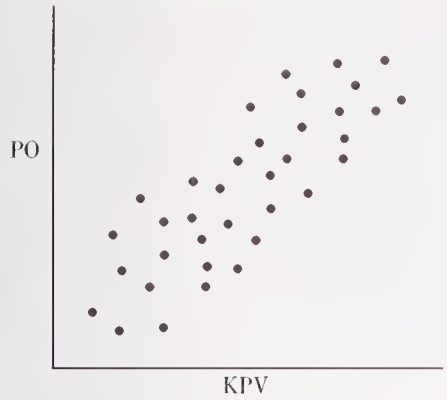
- Collect sets of paired data for the two factors being analyzed. A general rule is to collect at least 50 sets of paired data – the factors should be suspected of having a logical relationship, such as the relationship between a *process variable* and the *process outcome.*
- On graph paper, draw and label vertical (y) and horizontal (x) axes. Normally the process variable (potential cause) is put on the horizontal axis and the effect (process outcome) is put on the vertical axis.
- Scale the axes to spread the distance between the largest and smallest values of each factor over approximately equal distances. The measurement scales generally increase as you move up the vertical axis and to the right on the horizontal axis.
- Plot the paired sets of data by locating the intersection of their values and making a dot. If values are repeated, circle that point as many times as appropriate.
- Title the scatterplot and note the source, date and data collector.
- Interpret the data.

Analysis of Scatterplots

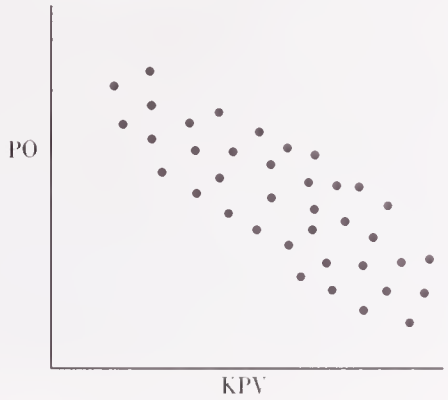
There are many levels of analysis that can be applied to scatterplots. The general shape of the data displayed can be analyzed to learn about the apparent type and strength of the relationship between the factors plotted. Scatterplots are often used to validate root causes of problems. The stronger the relationship, the greater the likelihood that change in one variable will affect change in another variable. The following illustrations show the various patterns and meanings that scatterplots can have.

Type of Relationship Outcome to Potential Cause

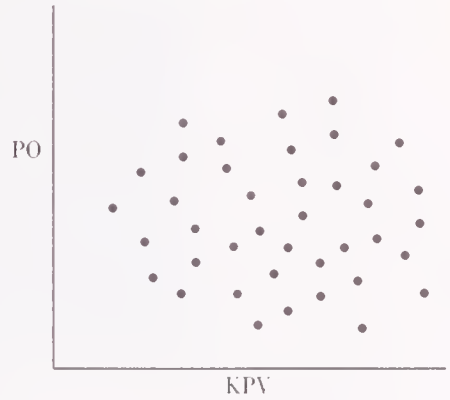
Increasing (Positive) Relationship



Decreasing (Negative) Relationship



No Apparent Relationship



Strength of the Relationship

If the data are tightly grouped, the variable appears to be responsible for most of the variation and the relationship appears to be very strong. If the data are loosely grouped, it is likely that other factors are greatly affecting the data. Outliers can be evidence of special causes in the process.

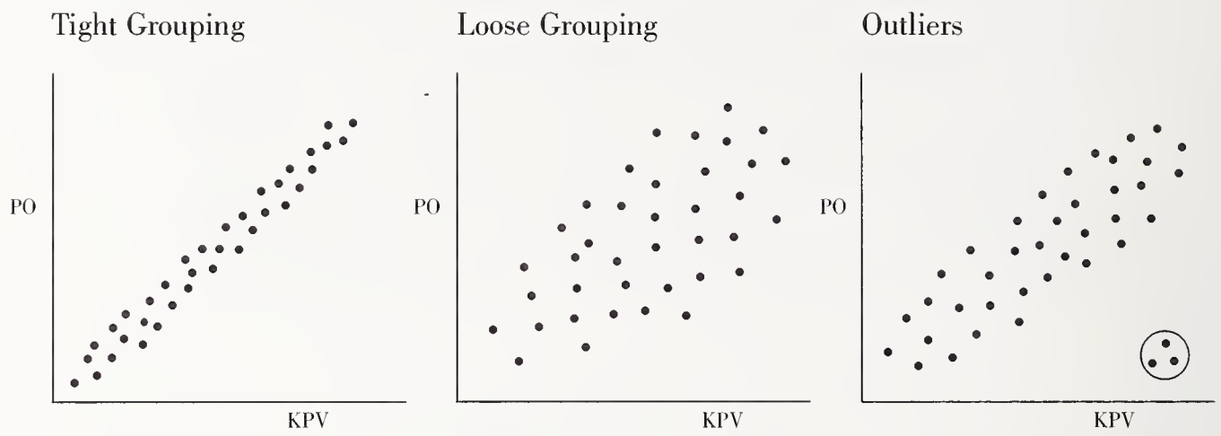
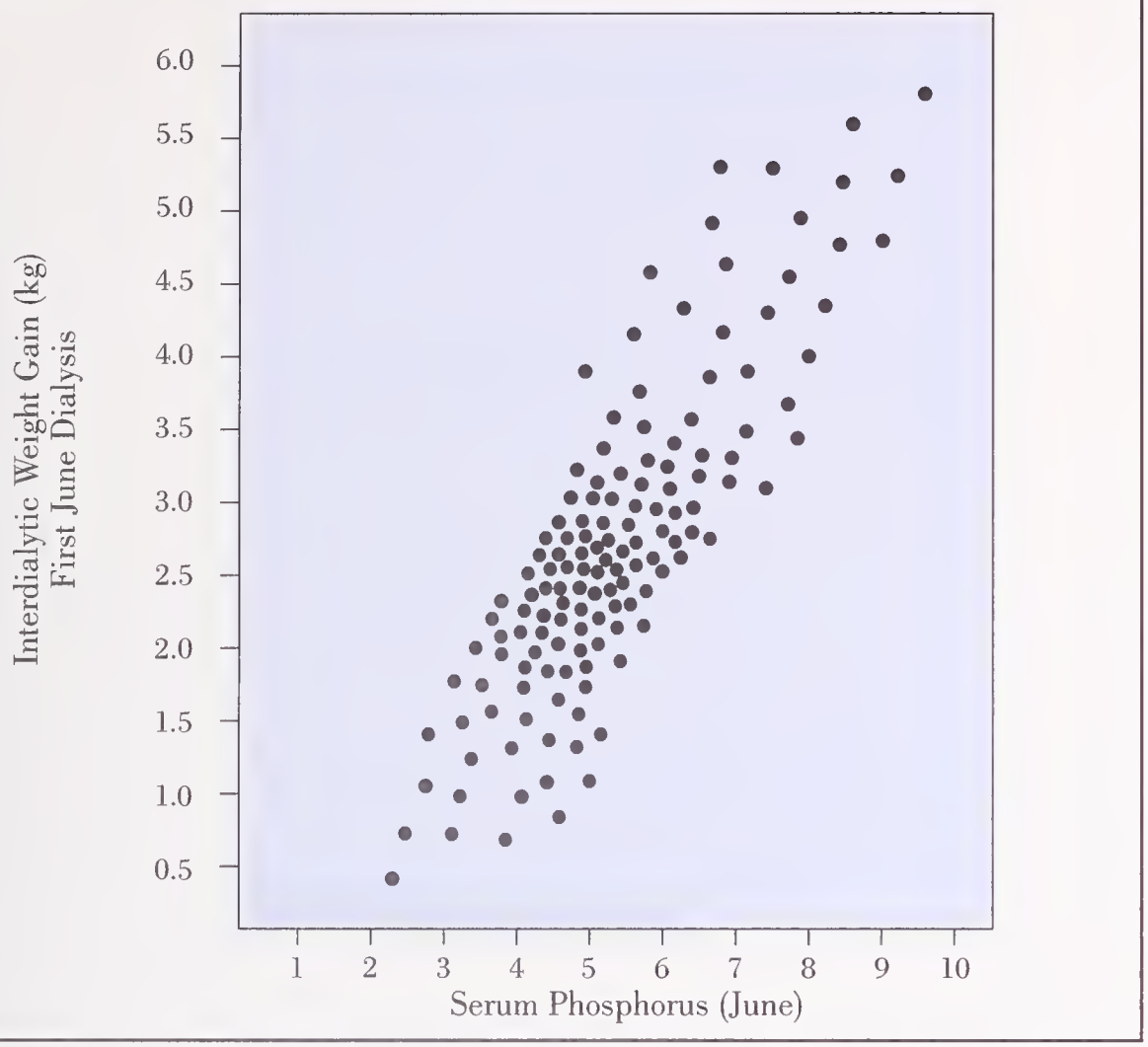


Fig. 20

SCATTER DIAGRAM



NOTES:

TECHNIQUES

BRAINSTORMING

What Brainstorming Is

A process for generating a list of ideas about an issue in a short amount of time.

Purpose

- Enables team members to creatively and efficiently generate a high volume of ideas on any topic.
- Improves team member involvement by reducing criticism and negativity.

The technique of brainstorming is maintained by five basic rules. However, the informality of the process generates an atmosphere of freedom. The rules are:

- No evaluation.
- Encourage *all* ideas.
- Hitchhike – build on the ideas of others.
- Strive for quantity.
- Do it quickly, five to ten minutes are often sufficient.

How to Brainstorm

The group leader presents the problem for which ideas are sought. The wording should encourage specific, tangible ideas not abstract ideas or opinions. The leader makes sure that the members understand the problem, the objective of the brainstorming session, and the process to be followed.

There are several methods of brainstorming. The most familiar is *unstructured* where group members call out their ideas spontaneously. (Ideas must not be discussed, criticized, or complimented.)

- Record each idea, as suggested, on a flip chart.
- Build and expand on ideas of others. (Encourage creative thinking, including innovative new ideas.)
- After all ideas are listed, clarify each idea, and eliminate exact duplicates.

Structured brainstorming requires each team member to give an idea in turn.

- The Leader or Recorder asks each member for an idea.
- Members may pass on any round.
- The session continues until all members have passed during the round.
- Ideas are recorded as in unstructured brainstorming.

The product of a brainstorming session will be a long list of ideas to be reviewed and evaluated. List reduction is often a next step.

Brainstorming Topic

Forty percent of the patients on hemodialysis have Urea Reduction Ratios (URRs) below 65%. What are some of the potential sources of problems?

Within five minutes, the project team generated the following list of ideas:

1. Patients cutting treatments short
2. Inadequate prescriptions
3. Poor blood flow
4. Access recirculation
5. Machine malfunctions
6. Inadequate heparinization
7. Unknown
8. Improper reuse
9. Inadequate staff training
10. Inadequate patient monitoring
11. Bad batch of dialyzers
12. Insufficient number of staff on duty
13. Larger dialyzers not available

NOMINAL GROUP TECHNIQUE (NGT)

What Nominal Group Technique Is

A ranking process used to build team consensus.

Purpose

- Allows a team to quickly come to a consensus on the relative importance of issues, problems, or solutions.
- Requires individual rankings of importance from each team member.
- Enables quiet team members to participate on equal footing.
- Makes a team's consensus (or lack of it) visible.

How to Do It

- Generate the list of issues, problems, or solutions to be prioritized.
- Individually list as many ideas as possible.
- Call out ideas from the lists in turn around the group.
- Write statements on a flip chart.
- Eliminate duplicates and/or clarify meanings of any statements. Record the final list of statements on a flip chart and use *letters* rather than numbers to identify each statement so that team members do not get confused by the ranking process that follows.
- Establish the ranking format. Using reverse order ranking, count total number of statements. If the total is 13, assign 13 as the most important and one as the least important.
- Each team member records the corresponding letters on a piece of paper and, using the agreed upon format, ranks the statements in order.
- Combine the rankings of all team members.

Examples of Nominal Group Technique

Group List

Why are average Urea Reduction Ratios so low?

Statement List

A. Patients cutting treatments short
B. Inadequate prescriptions
C. Poor blood flow
D. Access recirculation
E. Machine malfunctions
F. Inadequate heparinization
G. Unknown
H. Improper reuse
I. Inadequate staff training
J. Inadequate patient monitoring
K. Bad batch of dialyzers
L. Insufficient number of staff on duty
M. Larger dialyzers not available

An Individual Team Member's Ranking

A.	7	H.	3
B.	8	I.	6
C.	13	J.	10
D.	12	K.	11
E.	2	L.	9
F.	4	M.	5
G.	1		

Combined rankings of all team members

	Mary	Glenda	George	Jay	Geri		Total
A	6	5	8	7	7	=	33
B	7	10	9	12	8	=	46
C	13	13	13	11	13	=	63
D	11	8	11	13	12	=	55
E	1	3	2	4	2	=	12
F	3	4	5	3	4	=	12
G	2	1	1	1	1	=	6
H	4	2	3	2	3	=	14
I	5	6	4	5	6	=	26
J	10	12	10	10	10	=	52
K	12	11	12	9	11	=	54
L	9	9	7	8	9	=	51
M	8	7	6	6	5	=	32

Poor Blood Flow would be the highest priority. The team may choose to use this information in deciding which problem to address first, or to reduce a list in preparation for *validating their best guesses* (e.g., a data collection tool might be designed to validate the frequency of the occurrence of problems related to those statements with rankings of 40 or higher).

WEIGHTED VOTING (MULTIVOTING)

What Weighted Voting Is

One of several techniques used by teams to gain consensus on issues, problems, or solutions.

Purpose

- Reduce a list of ideas to a manageable number.
- *Rate* rather than rank choices (as in Nominal Group Technique).

How to Do It

- Follow steps as in outlined Nominal Group Technique.
- Generate a final list of *ideas* for voting.
- Label the ideas with letters.
- Decide on a value to use for voting – e.g., 100 points in total.
- Each member rates (distributes points) to those ideas of greatest importance. Each member can distribute the points among as many or as few choices as desired.
- Record and add the votes on a flip chart.
- Decide which ideas should receive further consideration.
- Ideas that receive no votes may be eliminated. Ideas with the highest votes are kept, as well as any other ideas about which any member feels strongly.
- If the list is still too long, a second vote may be taken.

FORCE-FIELD ANALYSIS

What Force-Field Analysis Is

A planning technique used to identify forces and factors in place that both help and hinder the solution of an issue or problem.

Purpose

- Forces the team to think together about all aspects of an issue or desired action.
- Encourages the team to agree on the relative priority of factors on each side of the balance sheet and to develop a solution strategy.
- Enables the team to reinforce the positives, and eliminate or reduce the negatives.

What Force-Field Analysis Looks Like

A large letter *T* is drawn on a flip chart with positive forces on one side and negatives on the other.

How to Do It

- Draw a letter *T* on a flip chart and write the issue on top of the *T*.
- Label the solid stem of the *T* as *present state.*
- Draw a broken line at the far right and label it *desired state.*
- Use *Brainstorming* or *Nominal Group Technique* to develop a list of helping forces to the left of the center line, the hindering forces to the right of the center line. These *forces* are often shown as arrows: The helping forces are pushing toward the *should-be* state, and the hindering forces are pushing away from it. It may be helpful to assess the relative strengths of both helping and hindering forces. Some groups use a scale (e.g., 5 = very strong, 4 = strong, 3 = medium, 2 = low, 1 = weak) to evaluate the relative impact of the forces. For graphic representation, proportionately sized arrows show relative strengths.
- Prioritize the driving forces that can be strengthened or identify restraining forces that would allow the most movement toward the ideal state if they were removed.

Once the analysis is complete, your group can use this information to generate potential solutions. Some ideas that the group can explore:

- How to increase the number or strength of the helping forces.
- How to decrease the number or strength of the hindering forces.

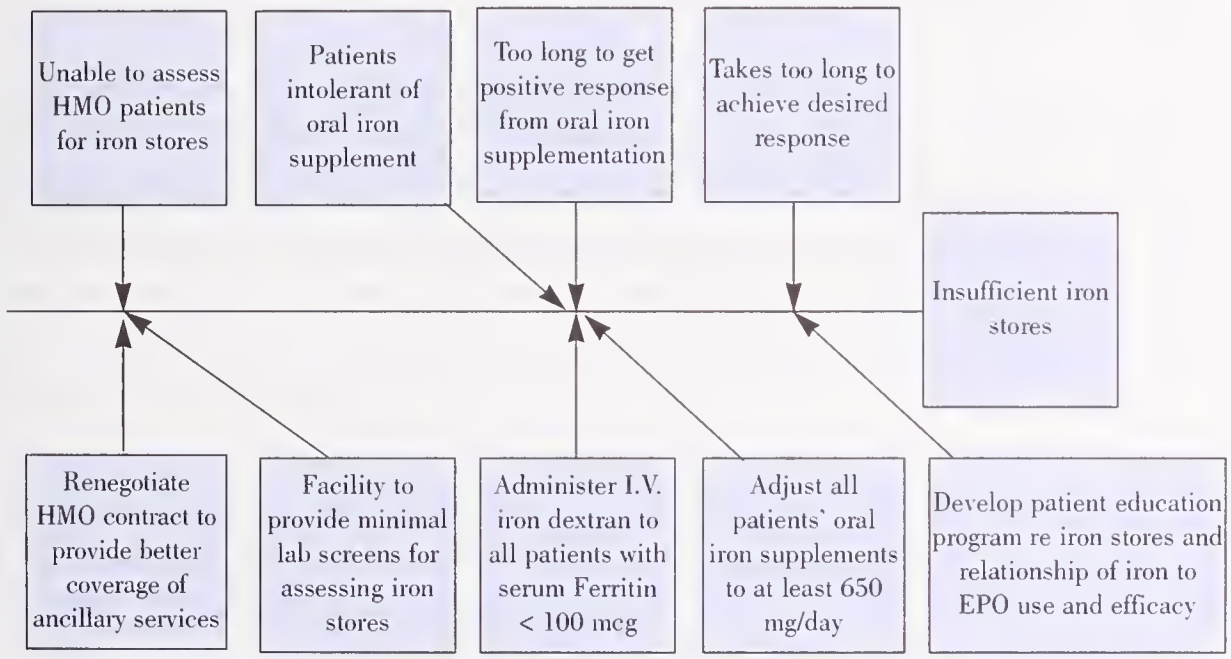
Fig. 22a **FORCE FIELD ANALYSIS**

As Is
Low Staff Morale in Dialysis Unit (rating 1.7) → *Desired State*
Increase morale (rating 4.0)

Helping	Hindering
Staff interviews →	← Inconsistent recognition
Small discussion groups well received →	← Inadequate numbers of staff
Quarterly recognition program →	← No management training
Problem-solving teams established →	← Outdated policies and procedures
	← Managers not involved in problem solving

Fig. 22b **FORCE FIELD ANALYSIS**

Graphic Example / Adaptation from Pilot Phase of Anemia Project



SELECTION MATRIX (CRITERIA RATING FORMS)

What A Selection Matrix Is

Grids to assist a team to find relationships between several approaches or sets of information and reach consensus.

Purpose

- Organizes the team to systematically identify, analyze and rate important decision factors (criteria).

How to Do It

If you've ever made a major purchase, such as a car or a house, you've probably used a criteria rating form. In buying a car, for example, you would consider criteria such as cost, mileage, comfort, trunk space, and repair record. If you listed these on a sheet of paper and rated (on a scale of 1 to 5) four cars you were considering on each of these factors, you would have constructed a criteria rating form. Adding the scores for each car gives you a relative rating of the cars under consideration.

Criteria can be treated equally, or they can be weighted relative to each other – e.g., with numerical numbers. Mileage may be three times more important than trunk space, and cost may be twice as important as mileage. In that case, the score for cost would be multiplied by six; likewise, the score for mileage would be multiplied by three. The scores for each factor are then added.

The following steps are useful in creating a selection matrix:

- Decide what factors or criteria are to be considered when evaluating the list of problems or solutions.
- Reach agreement on their definitions.
- Determine what (if any) weights should be assigned. Agree on the scale to be used (e.g., zero to three, one to five) to rate the options.
- Discuss each *cell* on the form to arrive at a consensus rating. It's best to look at all options (e.g., potential solutions) and rate them on a particular criterion at the same time (e.g., the group's ability to control the implementation of a solution). The group may determine that solution *C* provides the greater control. Assigning it the highest value then makes it easier to assign ratings to the other options, relative to solution *C*.

  Note: Sometimes scales are reversed to make it easier to compare options. For example, cost is a factor having a negative impact, so you may want to flip the scale: 5 = low cost, 1 = high cost.

When to Use A Selection Matrix

- In Step Three, to select the problem(s) for the group to tackle.
- In Step Five, as a means of evaluating the potential solutions generated in Step Four.

Point-Scoring Systems (also see Multivoting)

A point-scoring model is a variation of a criteria rating form. An arbitrary number of points is divided among the factors or criteria, in accordance with their relative importance. The group then reviews and discusses the options, assigning a number of points, up to the maximum for each category. The totals help to clarify the group's preferences.

How to Use a Point-Scoring System

- As in criteria rating forms, the first step is to determine (and define, if necessary) the criteria or factors to be used.
- Then distribute the points (100 or 1,000 are good numbers to use) among the factors, in proportion to their importance.
- Review all options with respect to the first factor, and decide, as a group, how many points to allocate to each. This number can range from zero to the maximum assigned to the factor. Looking at all the options with respect to a single factor allows the group to make relative judgments.

* Template available in Appendix.

Fig. 23 **SELECTION MATRIX***

Pilot Phase of Anemia Project

Possible Solutions	Cost Effective - 1 2 3 4 +	Value to Customer - 1 2 3 4 +	Can We Implement? Yes/No	Support Objectives? Yes/No	Can We Meet Deadline? (12/94)	Positive Effects EPO - 1 2 3 4 +	Adverse Effects - 1 2 3 4 + (worse)	No Compliance (Patient) Yes / No
Adjust all patients' oral iron supplements to at least 650 mg/day	Patient 1 Unit 4	4	Y	Y	N	4	3	N
Administer I.V. iron dextran to all patients with serum Ferritin <100 mcg	Patient 2 Unit 3	3	Y	Y	Y	3	3	Y
Facility to provide minimal lab screen for assessing iron stores	Patient 4 Unit 1	2	?	Y	?	1	1	Y
Renegotiate HMO contract to provide better coverage of ancillary services	Patient 3 Unit 3	3	?	?	?	1	1	N/A
Develop patient educational program re iron stores and relationship of iron to EPO use and efficacy	Patient 4 Unit 3	3	Y	Y	N	1	1	N

GLOSSARY

GLOSSARY

ALGORITHM	Graphic outlines, diagrams or flow charts that describe each step in the work or thought process.
ANEMIA	A condition occurring when the blood is deficient in red blood cells and/or hemoglobin which decreases the oxygen-carrying capacity of the blood.
ASSESS	To transform data into information by analyzing the data.
BRAINSTORMING	A group process technique designed to generate a large number of creative ideas through an interactive sequential process. Brainstorming is used to generate alternative ideas to be considered in making decisions.
CASE MIX	1. The combination of diagnoses, medical care, and social care needs present in the population of a health care facility. 2. The relative frequency of admissions of various types of patients, reflecting different needs for hospital resources. Some ways of measuring case mix are based on patient diagnoses or the severity of their illness, some on the utilization of services, and some on the characteristics of the hospital or area in which it is located (this is measurement by proxy rather than actual measurement).
CLINICAL ALGORITHM	A graphic outline that describes each step in the thought process of clinical diagnosis and treatment.
CLINICAL MEASURES	Data reported by the practitioner for specific patient care services.
COHORT	A population group that shares a common property, characteristic, or event, such as a year of birth or year of marriage. The most common one is the birth cohort, a group of individuals born within a defined time period, usually a calendar year or a five-year interval.
COMMON CAUSE VARIATION	Variation that is inherent in a process over time and that affects all outcomes and individuals. Its origin can usually be traced to an element of the system only management can correct. (JCAHO)
CONTINUOUS AMBULATORY PERITONEAL DIALYSIS (CAPD)	A type of peritoneal dialysis in which the patient dialyzes at home, using special supplies, but without a machine. (See Peritoneal dialysis)
CONTINUOUS CYCLING PERITONEAL DIALYSIS (CCPD)	A form of peritoneal dialysis which utilizes an automated cycler for delivering dialysis exchanges. (See Peritoneal dialysis)
CONTINUOUS PERITONEAL DIALYSIS	A regimen where peritoneal dialysate is present in the peritoneal cavity continuously, around the clock, seven days per week. Short interruptions between infrequent exchanges do not disqualify the regimen as continuous if the interruptions do not exceed ten percent of the total dialysis time.(See Peritoneal dialysis)

CONTINUOUS QUALITY IMPROVEMENT (CQI)	A structured organizational process for involving personnel in planning and executing a continuous stream of improvements in systems in order to provide quality health care that meets or exceeds customer expectations.
CONTROL LIMITS	Statistically determined points to identify the difference between common and special cause variation. The limits generally are three standard deviations above and below the mean.
CRITERIA	Expected level(s) of achievement, or specifications against which performance can be assessed.
CUSTOMER	Anyone who benefits from or is otherwise affected by the processes, products or services provided by others, including organizations.
DIALYSIS	A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.
DIALYSIS CENTER (RENAL)	A hospital unit that is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis) furnished directly or under arrangement.
DIALYSIS FACILITY (RENAL)	A unit (hospital-based or freestanding) which is approved to furnish dialysis service(s) directly to ESRD patients.
ESRD FACILITY	A facility which is approved to furnish at least one specific ESRD service. Such facilities are: renal transplantation center, renal dialysis center, renal dialysis facility, self-dialysis unit, and special purpose renal dialysis facility.
ESRD NETWORK	All Medicare-approved ESRD facilities in a designated geographic area specified by HCFA.
ESRD NETWORK ORGANIZATION	The administrative governing body to the ESRD Network and liaison to the Federal government.
ESRD service	The type of care or services furnished to an ESRD patient. Such types of care are: transplantation service, dialysis service, outpatient dialysis, staff-assisted dialysis, self-dialysis, home dialysis, and self-dialysis and home dialysis training.
HEALTH CARE QUALITY IMPROVEMENT PROGRAM (HCQIP)	An effort to develop and share with the renal community information on patterns of care and patterns of outcome that will lead to measurable improvements in the care and outcomes for ESRD Medicare beneficiaries.
HEMATOCRIT	A measurement of red blood cell volume in the blood.
HEMODIALYSIS	A method of dialysis in which blood from a patient's body is circulated through an external device or machine and then returned to the patient's bloodstream. Such an artificial kidney machine usually is designed to remove fluids and metabolic end products from the bloodstream by placing the blood in contact with a semipermeable membrane which is bathed on the other side by an appropriate chemical solution referred to as dialysate.

HISTOGRAM	A histogram takes measurement data and displays its distribution; it reveals the amount of variation that any process has within it.
IMPROVE	To take actions that result in the desired measurable change in the identified performance dimension.
IMPROVEMENT PLAN	A plan for measurable process or outcome improvement. This plan is usually developed cooperatively by a provider and the Network. The plan must address how and when its results will be measured.
INCIDENCE	The frequency of new occurrences of a condition within a defined time interval. The incidence rate is the number of new cases of specific disease divided by the number of people in a population over a specified period of time, usually one year.
INDICATOR	A key quality characteristic used to measure, over time, the performance of functions, processes, and outcomes of an organization.
INTERMITTENT PERITONEAL DIALYSIS	An intermittent (periodic), supine regimen, which uses intermittent flow technique, automated, assisted manual, or manual method in dialysis sessions two to four times weekly.
MEAN	A measure of central tendency of a collection of data consisting of the sum of all measurements of the data divided by the total number of measurements in the data set; also called average.
MEASURE	To collect quantifiable data about a dimension of performance of function or process.
MEASUREMENT	The systematic process of data collection, repeated over time or at a single point in time.
MEDIAN	A set of measurements defined to be the middle value when the measurements are arranged from the lowest to the highest.
MODALITY	The methods of treatment for kidney failure/ ESRD. Modality types include transplant, hemodialysis and peritoneal dialysis.
MONITORING	A planned, systematic and ongoing process to gather and organize data, and aggregate results.
MORBIDITY	A diseased state; often used in the content of a *morbidity rate*, i.e., the rate of disease or proportion of diseased people in a population. In common clinical usage, any disease state, including diagnoses and complications, is referred to as morbidity.
MORBIDITY RATE	The rate of illness in a population. The number of people ill during a time period divided by the number of people in the total population.

MORTALITY RATE	The death rate, often made explicit for a particular characteristic, e.g., gender, sex, or specific cause of death. Mortality rate contains three essential elements: 1. The number of people in a population group exposed to the risk of death (the denominator). 2. A time factor. 3. The number of deaths occurring in the exposed population during a certain time period (the numerator).
MULTIDISCIPLINARY MEMBERS	Team members selected from all disciplines directly involved in or affected by the process being investigated.
OUTCOME	The result of the performance (or nonperformance) of a function or process.
OUTCOME INDICATOR	An indicator that assesses what happens or does not happen to a patient following a process; agreed upon desired patient characteristics to be achieved, or undesired patient conditions to be avoided.
OUTCOMES ASSESSMENT	Health outcomes go beyond the traditional measures of mortality and complications to include the patient's physiology, signs and symptoms, functional status, and well-being. An outcomes assessment effort focuses on measuring these constructs, monitoring patients over time, and giving clinicians feedback about results to help them optimize the process of care. (JCAHO, 1994)
PARADIGM SHIFT	A paradigm is an example serving as a fixed model. When the model is altered by process, a new paradigm is formed creating a shift in the paradigm or example.
PERFORMANCE	The way in which an individual, group or organization carries out or accomplishes its important functions or processes.
PERFORMANCE ASSESSMENT	Involves analysis and interpretation of performance measurement data to transform it into useful information for purposes of continuous performance improvement.
PERFORMANCE IMPROVEMENT MONITORING SYSTEM	Ongoing system focused on high-risk, high-volume and/or problem-prone issues that affect patient care quality; used to identify and resolve problems.
PERFORMANCE MEASURE	A measure, such as a standard or indicator, used to assess the performance of a process or function of any organization.
PERITONEAL DIALYSIS	A procedure that introduces dialysate into the abdominal cavity to remove waste products through the peritoneum (a membrane which surrounds the intestines and other organs in the abdominal cavity). It functions in a manner similar to that of the (artificial) semipermeable membrane in the hemodialysis machine. Three forms of peritoneal dialysis are continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis, and intermittent peritoneal dialysis.
PRACTICE GUIDELINES	Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions. (AHCPR, 1992)

PREVALENCE	The number of existing cases of a disease or condition in a given population at a specific time.
PROCESS	A goal-directed, interrelated series of actions, events, mechanisms or steps.
PROCESS IMPROVEMENT	A methodology utilized to make improvements to a process through the use of continuous quality improvement methods.
PROCESS INDICATOR	An indicator that measures a process.
PROFILES	Data aggregated by specific time period (e.g., quarterly, annually) and target area (e.g., facility, state) for the purpose of identifying patterns.
REFERENCE DATABASE	A organized collection of similar data from many sources that can be used to compare an organization's performance to that of others.
ROOT CAUSE	The primary cause of the problem being addressed and toward which the solution is directed.
QUALITY CONTROL	A management process whereby performance is measured against expectations and corrective actions are taken.
SCATTER DIAGRAM	A scatter diagram is used to study the possible relationship between one variable and another. It is used to test for possible cause-and-effect relationships. It cannot prove that one variable causes another, but it does make it clear whether a relationship does exist and the strength of that relationship.
SELECTION MATRICES	Diagrams used to weigh options; to narrow down options through a systematic approach of comparing choices by selecting, weighing and applying criteria.
SELF-CARE SERVICES	Services provided by a dialysis facility or center in which patients who have been trained to perform self-dialysis do so with little or no professional assistance.
STANDARDS OF CARE	Statements of patient care expectations; the kinds of care patients can expect to receive from health care personnel. (Claflin, 1993)
STANDARDS OF PRACTICE	Statements of expectation for health care providers; what health care providers must do to meet the standards of care or patient expectations. (Claflin, 1993)
STORYBOARD/STORYBOOK	Tools used to record and display the team's progress. Storyboards vary in size and may be posted in staff lounges or other visible areas. Each phase is summarized, then updated. A more detailed version is called the storybook. It may include raw data and minutes from team meetings.
SYSTEMATIC	Pursuing a defined objective(s) in a planned, step-by-step manner.

TEAM FACILITATOR/ADVISOR	A person, trained in the scientific approach of total quality management and in working with groups, who helps the group stay focused. The advisor serves as a process guide, teacher of quality improvement methods, and consultant to the team leader, and helps connect the work to the knowledge necessary for improvement. The facilitator may not be a part of the process being improved (has no ownership of topic).
TEAM	A group of usually five to eight people from two or more areas of the facility who are addressing an issue that impacts the operations of each area; consists of a leader, facilitator, and members.
TEAM LEADER	Responsibilities include preparing and conducting meetings, assigning responsibilities to members, providing direction and representing the group to management. The team leader is also a team member.
TOTAL QUALITY MANAGEMENT/ CONTINUOUS QUALITY IMPROVEMENT	A management philosophy for continually improving quality and satisfying customers that is directed from the top levels of the organization and involves all its members in the improvement process, products and services.
VARIANCE	A measure of the differences in a set of observations.
VARIATION	The differences in results obtained in measuring the same phenomenon more than once. The sources of variation in a process over time can be grouped into two major classes: common causes and special causes.
X-AXIS	The horizontal axis in a chart; the items being measured.
Y-AXIS	The vertical axis in a chart; contains the numerical range of the items being measured.

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REFERENCES

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SUPPLEMENTAL READING

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NOTES:

CHECKLISTS

CHECKLIST FOR STEP ONE

At the end of Step One, the team should have accomplished the following activities and reached consensus on the answers to the following questions:

- ☑ Assembled a team and conducted orientation meetings.
- ❑ Discussed team roles and reviewed team guidelines.
- ❑ Identified a team leader.
- ❑ Assigned team roles and responsibilities.
- ❑ Identified a format for reporting team progress.

  Has the group discussed team roles and reviewed team guidelines to the satisfaction of all team members?
- ❑ Discussed the aim of the project.
- ❑ Selected a quality improvement methodology.

  Does everyone on the team share a common understanding of the HCQIP project?
- ❑ Identified customers of the process improvement project: HCFA and patients.
- ❑ Identified and discussed customer expectations.

  – Measure organizational performance with median facility hematocrits.

  – Improve the anemia status of dialysis patients.

  Does everyone in the group understand why this aspect of care was chosen for process improvement?
- ❑ Instituted team training.

  – Read the Guide.

  – Practice team behavioral techniques.

  – Practice tools development.

  – Encouraged supplemental reading.

  Does everyone in the group have a common understanding of the recommended tools and techniques for process investigation and improvement?

CHECKLIST FOR STEP TWO

At the end of Step Two the team should have accomplished the following activities and reached consensus on the answers to the following questions:

- ☑ Reviewed Anemia Profile Report.
- ❑ If needed, requested clarification of the data from the Network Office.
  Does everyone understand the HCFA comparative data?
- ❑ Planned and designed a current data sample and instruments for data collection.
- ❑ Assigned responsibility for data collection.
- ❑ Established a time frame for completion of the data collection.
- ❑ Instituted data collection.
  Does everyone agree that the new data accurately reflect current performance?
- ❑ Prepared data displays.
- ❑ Conducted meetings to review new data.
  Have we established an acceptable procedure and data format to plot data regularly (at least monthly)?
- ❑ Selected a format for reporting progress.
  Does everyone understand the progress reporting format?
- ❑ Written an opportunity statement.
  Does everyone agree that the opportunity statement is written in objective terms stating both the "as is" as well as the "desired state" of performance?

CHECKLIST FOR STEP THREE

At the end of Step Three the team should have accomplished the following activities and reached consensus on answers to the following questions:

- ☑ Discussed the concept of variation.

  Was the team able to identify examples of both common cause and special cause variation?

- ❑ Developed a flow chart of the process.

  Has the process for managing anemia been fully and accurately described?

- ❑ Compared the facility's process to others.

  Have appropriate external references been used to compare practice?

- ❑ Identified sources of variation.

  Have all potential sources of variation been identified?

- ❑ Collected and analyzed data.

  Were major sources of variation confirmed?

- ❑ Selected ONE source of variation for further investigation and action.

  Does the team agree that this is a valid problem over which the team can exert some control or influence?

- ❑ Collected additional monitoring data.

  Has the team continued to monitor the process by updating the run chart?

- ❑ Reported team progress.

  Has progress report, storyboard or storybook been updated appropriately?

CHECKLIST FOR STEP FOUR

At the end of Step Four the team should have accomplished the following activities and reached consensus on the answers to the following questions:

- ☑ Identified a major source of process variation.
  Did we begin with a confirmed source of problems (variation)?
- ❑ Developed a flow chart for the subprocess associated with the confirmed source of variation.
- ❑ Brainstormed for possible root causes of variation.
  Have we adequately described and analyzed all potential causes of the confirmed source of variation?
- ❑ Executed a data collection cycle.
  Have we confirmed that these root causes are real?
- ❑ Displayed and analyzed data.
  Have we ranked the confirmed root causes (Pareto analysis)?
- ❑ Selected a root cause for improvement planning.
  Did we revisit the Opportunity Statement for the desired state?
- ❑ Sought feedback from members outside of the team.
  Do we all agree on the specific area(s) (root causes) chosen for improvement?
- ❑ Continued monitoring process.
  Are we continuing to monitor the process and update the run chart?
- ❑ Continued progress reporting.
  Have we updated our progress report (storyboard/storybook?)

CHECKLIST FOR STEP FIVE

At the end of Step Five the team should have accomplished the following activities and reached consensus on the answers to the following questions:

- ☑ Brainstormed as many solutions as possible.
  Did we fully explore divergent opinions?
- ❑ Identified a best solution.
  Did we gain consensus without pressuring?
- ❑ Identified the actions needed to implement the solution.
  Do our plans include assignment of responsibilities and due dates?
- ❑ Developed an evaluation plan which includes criteria for evaluating the trial and time lines.
  Have we developed an evaluation plan to determine to what extent the desired state has been achieved?
- ❑ Implemented the trial.
- ❑ Monitored the process.
  Are we continuing to monitor the process and update the run chart?
- ❑ Reported progress.
  Have we updated our progress report?

CHECKLIST FOR STEP SIX

At the end of Step Six the team should have accomplished the following activities and reached consensus on the answers to the following questions:

- ☑ Collected data according to the plan.

  Was the trial improvement carried out correctly?
  Did we do what we said we were going to do?

- ❑ Analyzed the data.

  Was the monitoring process adequate?

- ❑ Evaluated the solution.

  Did the process improve? Did we do it the right way?
  Did it make a difference?

- ❑ Checked for new problems created by the solution.

  Were new problems identified?

- ❑ Addressed new problems or causes as needed.

  What unexpected findings were present?

- ❑ Agreed that the trial improvement was successful.

  Are we ready to change the system?

- ❑ Agreed that the trial improvement was not successful.

  Do we have team commitment to recycle back to search for another root cause?

- ❑ Presented initial results to management for consideration of further action.

  Does management agree that the trial solution should be implemented systemwide?
  Does management agree that the project team should cycle back to continue to search for root causes?

- ❑ Continued to monitor the process.

  Are we continuing to monitor the process and update the run chart?

- ❑ Updated the progress report.

  Are we ready to report the results of this project to others?

CHECKLIST FOR STEP SEVEN

At the end of Step Seven, the team should have accomplished the following activities and reached consensus on answers to the following questions:

- ☑ Acted on results, after consulting management.

  Has management agreed to implement and support systemwide change?

  Do all members of the project team agree to return to search for other sources and root causes of process variation?

- ❑ Prepared a report of the results of the project.

  Have all team members participated in preparing the report?

- ❑ Communicated results.

  Have the results been communicated to all staff?

TEMPLATES

Checksheet for Baseline Hematocrit Data Collection

Patient ID	Check if on EPO	_____ HCT month	_____ HCT month	_____ HCT month
Mean for all patients				
Mean for patients on EPO				
Mean for patients not on EPO				

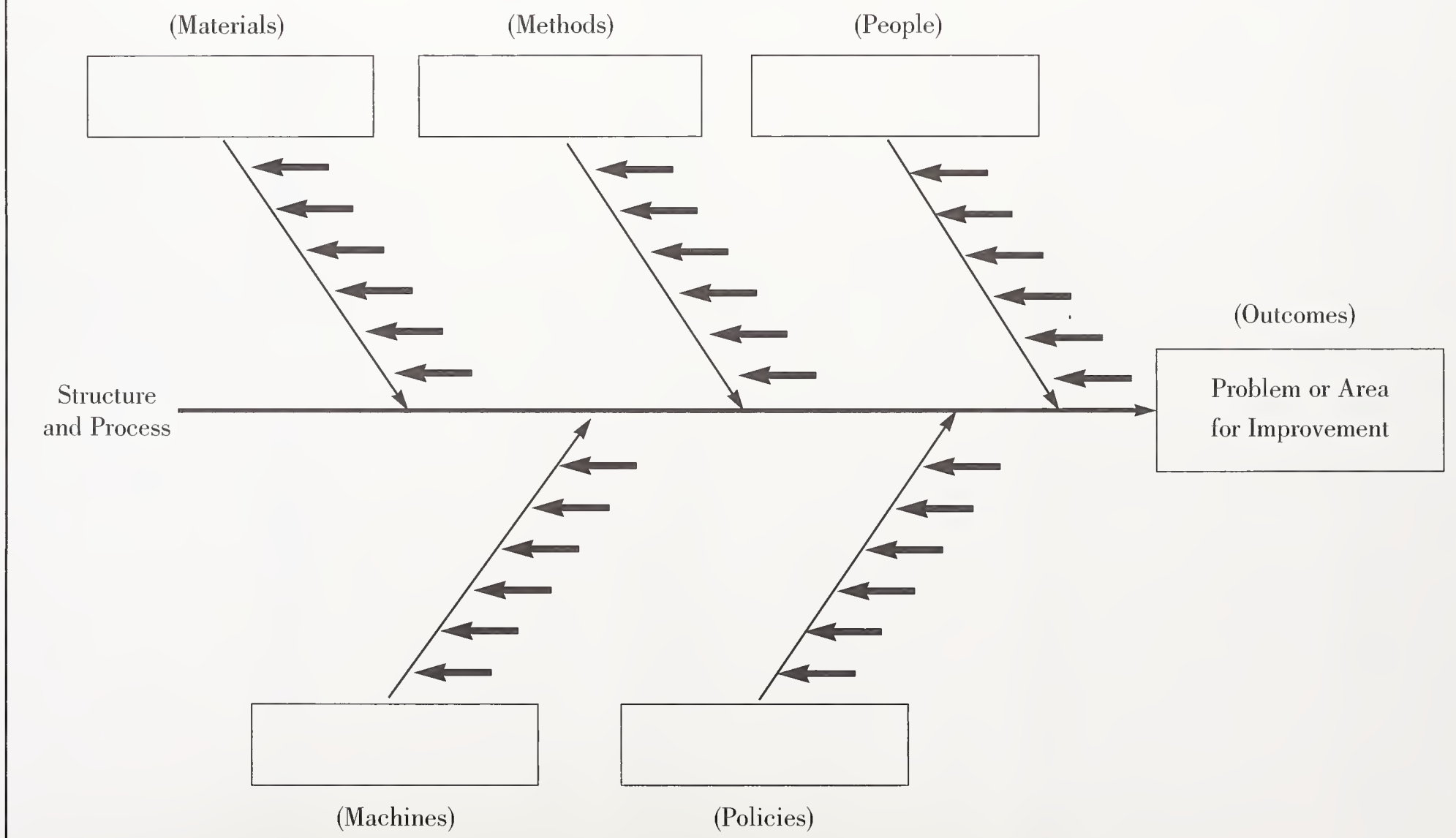
STORYBOARD FORMAT FOR SEVEN-STEP APPROACH

Step One: Commit to Improve Care	Step Two: Clarify Knowledge of Process Performance and Identify Opportunity to Improve

Step Three: Analyze Process and Identify Sources of Variation

Step Four: Search for Root Causes and Select an Area for Improvement	Step Five: Design and Implement Improvement Trial
Step Six: Evaluate Improvement Trial and Initiate Change	**Step Seven: Communicate Results**

CAUSE-AND-EFFECT DIAGRAM



CHECKSHEET FOR CAUSES OF ANEMIA

Patient Sample: All patients with HCT < 32% on <u>two</u> or more occasions _____, 199__
date

FACTORS ↓PATIENT ID→						AGGREGATE		
Modality						HD	PD	ALL
Hematocrit								
Dialysis Factors								
Inadequate Dialysis								
Clotted Disposable								
Blood Loss 2° Procedure								
Methods/Materials								
Inadequate Iron Replacement/Stores								
Imferon Given								
Oral Fe Preparation Prescribed								
EPO Dose Held or Reduced								
Lab Error								
EPO Administration Time						before	end	after
EPO Supply Depleted								
EPO Route						SQ		IV
Personnel								
Wrong EPO Dose								
Patient Factors								
Volume Expansion								
On EPO < 3 Months								
Co-Morbidities								
Hemolysis								
GI Bleed								
Surgery								
Poor Nutrition								
Malignancy								
↑ Al^{+++}								
↑ PTH								
Infection								
Platelet Dysfunction								
Other Anemia Causes (Hemoglobinopathy, B_{12}, Folate or Pyridoxine Deficient)								

Problem Selection Worksheet

Directions: In boxes across the top, write the problems your group is considering. Then rate them against the listed criteria by working across each row. The higher the total score, the greater the likelihood that the problem is appropriate for your group to work on.

Problem Statement →				
Control 1 2 3 4 5 Little Great				
Importance 1 2 3 4 5 Little Great				
Difficulty 1 2 3 4 5 Little Great				
Time 1 2 3 4 5 Little Great				
Resource Requirements 1 2 3 4 5 Little Great				
Total Points				

Control: The extent to which the group controls the problem and can control the situation.

Importance: The seriousness of the problem.

Difficulty: A judgment about the relative difficulty of working through the problem to a solution.

Time: A judgment about the relative length of time it will take to resolve the problem.

ROI: The approximate, expected payoff from solving the problem.

Resources: The amount of resources required to solve the problem – people, time, money, equipment, etc.

TEAM ACTION PLAN FORM

Problem Description:

Improvement Goal:

Proposed Solution:

What	Who	Target Date	Comments
1.			
2.			
3.			
4.			
5.			
6.			

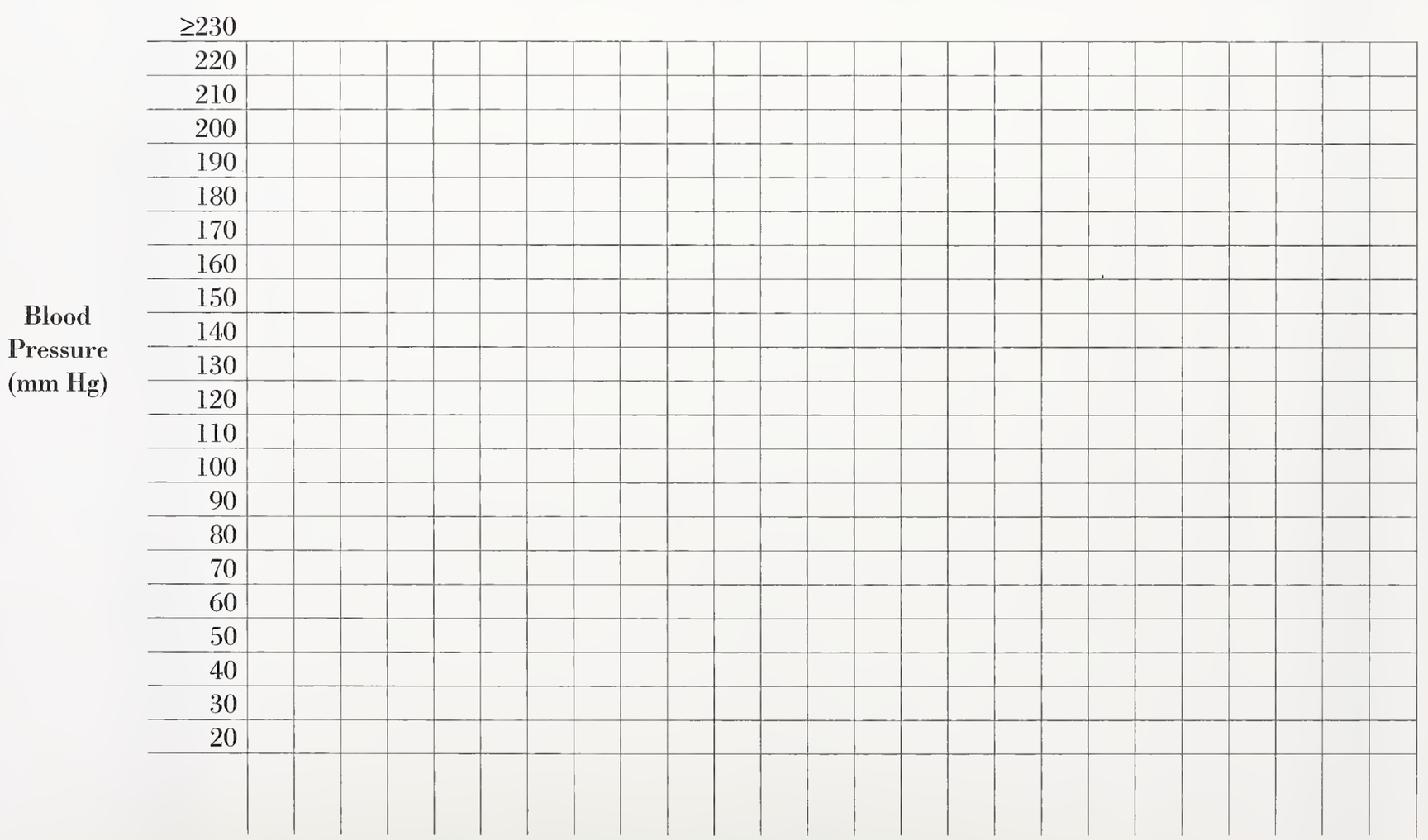
PARETO WORKSHEET			
Causes/Factors	# Occurrences	% of Total	Cumulative %
Total of All Causes (denominator)			

HEMATOCRIT/EPOGEN® (Epoetin alfa) DOSE RUN CHART

HCT (%)	Dose (units)
≥38	
37	10,000
36	9500
35	9000
34	8500
33	8000
32	7500
31	7000
30	6500
29	6000
28	5500
27	5000
26	4500
25	4000
24	3500
23	3000
22	2500
21	2000
20	1500
19	1000
≤18	

Date

BLOOD PRESSURE RUN CHART



PARETO CHART

MONITORING FORM

Patient Monitoring Form For Anemia Management

Start Date _____ Data Collector _____

Record first values of the month. If none found, record "0".

MONTHS											
1	2	3	4	5	6	7	8	9	10	11	12

OUTCOME INDICATOR	DESIRED VALUE	ACTUAL VALUE
HCT CURRENTLY	> 31%	
PROCESS VARIABLE		
FERRITIN	> 100 g/mL	
TRANSFERRIN SATURATION	> 20%	
NUTRITIONAL ASSESSMENT	Alb > 3.5	
BLEEDING DURING PAST MONTH (Y/N)	N	
INFECTION OR INFLAMMATION DURING PAST MONTH(Y/N)	N	
OTHER		
Comments:		

FIGURES

HCFA REGIONAL OFFICES & ESRD NETWORKS

HCFA OFFICES:

HCFA – Central Office
Health Standards and Quality Bureau
S2-11-07
7500 Security Boulevard
Baltimore, MD 21244
Phone: 410-786-6853

HCFA – Region I
Division of Health Standards
and Quality
Medical Review Branch
JFK Federal Building, Room 2275
Boston, MA 02203
Phone: 617-565-3136

HCFA – Region VI
Division of Health Standards
and Quality
Medical Review Branch
1200 Main Tower Building,
Room 1935
Dallas, TX 75202
Phone: 214-767-6327

HCFA – Region VII
Division of Health Standards
and Quality
Medical Review Branch
New Federal Office Building
601 East 12th Street, Room 242
Kansas City, MO 64106
Phone: 816-426-5746

HCFA – Region X
Division of Health Standards
and Quality
Medical Review Branch
2201 Sixth Avenue, Mail Stop RX-42
Seattle, WA 98121
Phone: 206-615-2317

ESRD NETWORKS:

ESRD Network Organization No. 1
PO Box 9484
New Haven, CT 06534
Phone: 203-387-9332;
Fax: 203-389-9902
HCFA Region I: Maine, New
Hampshire, Vermont, Massachusetts,
Connecticut, Rhode Island

ESRD Network Organization No. 2
1216 Fifth Avenue, Room 456
New York, NY 10029
Phone: 212-289-4524;
Fax: 212-289-4732
HCFA Region I: New York State

ESRD Network Organization No. 3
Cranbury Plaza
2525 Route 130, Building C
Cranbury, NJ 08512
Phone: 609-395-5544;
Fax: 609-655-4332
HCFA Region I: New Jersey, Puerto
Rico, U.S. Virgin Islands

ESRD Network Organization No. 4
University of Pittsburgh
Medical Center
200 Lothrop Street
Pittsburgh, PA 15213-2582
Phone: 412-647-3428;
Fax: 412-683-6814
HCFA Region I: Pennsylvania,
Delaware

ESRD Network Organization No. 5
1527 Huguenot Road
Midlothian, VA 23113
Phone: 804-794-3757;
Fax: 804-794-3793
HCFA Region I: District of Columbia,
Maryland, Virginia, West Virginia

ESRD Network No. 6
Lake Plaza East
900 Ridgefield Drive, Suite 150
Raleigh, NC 27609
Phone: 919-876-7545;
Fax: 919-876-9433
HCFA Region VI: Georgia, North
Carolina, South Carolina

ESRD Network Organization No. 7
1 Davis Blvd., Suite 304
Tampa, FL 33606
Phone: 813-251-8686;
Fax: 813-251-3744
HCFA Region VI: Florida

ESRD Network Organization No. 8
PO Box 55868
Jackson, MS 39396-5868
Phone: 601-936-9260;
Fax: 601-932-4446
HCFA Region VI: Alabama,
Mississippi, Tennessee

ESRD Network Organization No. 9
911 East 86th Street, Suite 202
Indianapolis, IN 46240
Phone: 317-257-8265;
Fax: 317-257-8291
HCFA Region VII: Kentucky,
Indiana, Ohio

ESRD Network Organization No. 10
911 East 86th Street, Suite 202
Indianapolis, IN 46240
Phone: 317-257-8265;
Fax: 317-257-8291
HCFA Region VII: Illinois

ESRD Network Organization No. 11
970 Raymond Avenue, Suite 205
St Paul, MN 55114
Phone: 612-644-9877;
Fax: 612-644-9853
HCFA Region VII: Michigan,
Minnesota, Wisconsin, North Dakota,
South Dakota

ESRD Network Organization No. 12
North Point Circle 2, Suite 105
7509 NW Tiffany Springs Parkway
Kansas City, MO 64153
Phone: 816-880-9990;
Fax: 816-880-9088
HCFA Region VII: Missouri, Iowa,
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